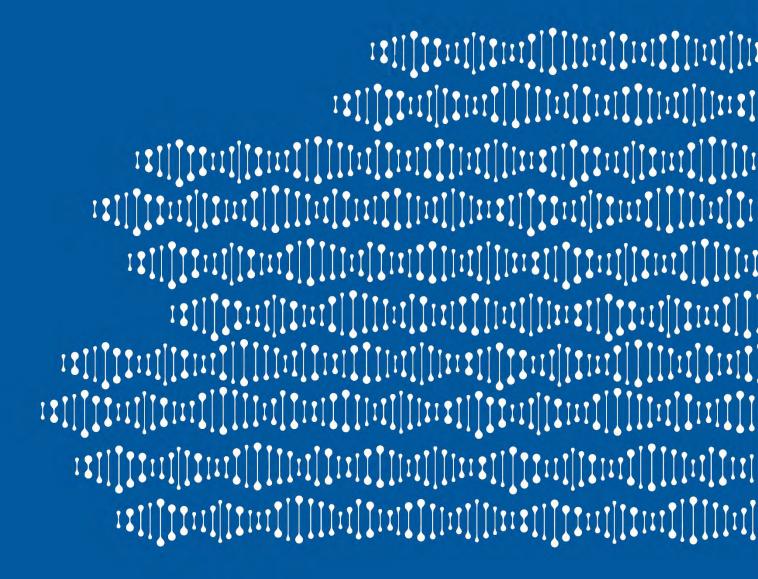
Proposed Grant Awards

May 20, 2020





MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS

FROM: JAMES WILLSON, M.D., CHIEF SCIENTIFIC OFFICER

SUBJECT: ACADEMIC RESEARCH RECRUITMENT AWARD

RECOMMENDATIONS FY2020, REC CYCLE 20.7, 20.8 AND 20.9.

DATE: MAY 20, 2020

The Program Integration Committee (PIC) has completed its review of the recommendations forwarded by the Scientific Review Council (SRC) for FY2020 recruitment cycles 20.7, 20.8 and 20.9, Note grant application RR200050 was withdrawn by the nominating institution on May 1, 2020. The PIC recommends 13 awards from three grant mechanisms totaling \$41,973,674, as displayed in Table 1. Note applications are ranked by overall score.

Table 1:

Grant Mechanism PIC Recommend				
	Awards	Funding		
Recruitment of Established Investigators	4	\$22,073,674		
Recruitment of Rising Stars	2	\$8,000,000		
Recruitment of First-Time, Tenure Track Faculty Members	7	\$11,900,000		
Total	13	\$41,973,674		

Program Priorities Addressed:

The applications proposed to the Program Integration Committee for funding address the following Academic Research Program Priorities: recruitment of outstanding cancer researchers to Texas, computational biology and analytic methods, disparities, childhood cancers, and hepatocellular cancers. The program priorities addressed by the proposed slate of awards are displayed in Table 2 and Attachment 1.

Table 2

Program Priorities Addressed by Grant Recommendations							
# Awards*	Funding*						
14	Recruitment of outstanding cancer researchers to Texas	\$43,973,674					
1	Childhood Cancers	\$5,073,674					
1	Computational biology and analytic methods	\$2,000,000					
1	Disparities	\$6,000,000					

1	Hepatocellular Cancer	\$6,000,000			
1	Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions	\$500,000			
*Some grant awards address more than one program priority and are double counted.					

1. RECRUITMENT OF ESTABLISHED INVESTIGATORS SLATE FY20.7, FY20.8 and FY20.9

Peer Review Recommendations

The applications were evaluated and scored by the Scientific Review Council (SRC) to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Purpose of Recruitment of Established Investigators Awards: The aim is to recruit outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.

Funding levels for Recruitment of Established Investigators Awards:

Up to \$6 million over a period of 5 years.

Recommend Awards:

Seven Recruitment of Established Investigators grant applications were submitted and four were recommended by the Scientific Review Council for an award.

RR200057

Candidate: Dean Felsher, M.D., Ph.D.

Funding Mechanism: Recruitment of Established Investigator

Applicant Organization: The University of Texas M. D. Anderson Cancer Center

Original Organization of Nominee: Stanford University

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.2

Recommended Total Budget Award and Duration: \$6,000,000

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas,

Hepatocellular Cancer.

Description:

Dean Felsher, M.D., Ph.D., an internationally renowned physician scientist, is recommended for a CPRIT Established Investigator Award to support his recruitment to M.D. Anderson Cancer Center from Stanford. Dr. Felsher has made major contributions to understanding the role of the MYC oncogene in tumorigenesis and to validating the concept of oncogene addiction in experimental MYC-driven osteosarcoma and hepatocellular cancer. He has a stellar record of

productivity and a strong record of peer reviewed funding and mentorship. At M.D. Anderson, his research program will focus on identification of new therapies that target the MYC pathway in hepatocellular cancer, T cell leukemia, and renal cell cancer.

RR200072

Candidate: Wenyi Wei, Ph.D.

Funding Mechanism: Recruitment of Established Investigator

Applicant Organization: The University of Texas Southwestern Medical Center

Original Organization of Nominee: Beth Israel Deaconess Medical Center, Harvard Medical

School

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.5

Recommended Total Budget Award and Duration: \$6,000,000

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Description:

Wenyi Wei, Ph.D., a leading cancer biologist, is recommended for a CPRIT Established Investigator Award to support his recruitment to UT Southwestern from the Harvard Medical School and Beth Israel Deaconess Medical Center. Dr. Wei investigates the signal transduction pathways in cancer and their exploitability for novel anti-cancer therapeutics. His research is highly complementary with the UT Southwestern environment where he plans to interact with James Chen, James Brugarolas and Carlos Arteaga, among others.

RR200046

Candidate: Henry Charles Manning, Ph.D.

Funding Mechanism: Recruitment of Established Investigator

Applicant Organization: The University of Texas M. D. Anderson Cancer Center

Original Organization of Nominee: Vanderbilt University Medical Center

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.0

Recommended Total Budget Award and Duration: \$5,000,000

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Description:

Charles Manning, Ph.D., an accomplished radiochemist, is recommended for a CPRIT Established Investigator Award to support his recruitment to M.D. Anderson from Vanderbilt. Dr. Manning is currently a Professor of Radiology, Neurosurgery, Biomedical Engineering, and Chemistry at Vanderbilt. Dr. Manning's research is at the intersection of positron emission tomography (PET) radiochemistry, molecular imaging and cancer metabolism and he is leading the development of next generation cancer therapeutic and targeted cancer imaging agents.

RR200043

Candidate: Tanmay Lele, Ph.D.

Funding Mechanism: Recruitment of Established Investigator

Applicant Organization: Texas A&M Engineering Experiment Station

Original Organization of Nominee: University of Florida

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.8

Recommended Total Budget Award and Duration: \$5,073,674

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas, Computational biology and analytic methods, and Childhood Cancers (medulloblastoma).

Description:

Tanmay Lele, Ph.D., an accomplished cell biologist trained in chemical engineering, is recommended for a CPRIT Established Investigator Award to support his recruitment to Texas A&M Engineering Experiment Station from the University of Florida. His work is focused on the role of mechanical forces in shaping a cell's nuclear structure and the relationship of this to gene expression to answer a key question in cancer biology- why the nucleus is almost always abnormal in cancer cells. He holds a named professorship at the University of Florida and is extremely well-funded, most recently by a Physical Sciences U01 from the NCI that supports a transdisciplinary team linking physical scientists and cancer biologists. At Texas A&M he plans to further develop his methods that combine microscopy and advanced mathematical image analysis in partnership with cancer scientists at the Texas Medical Center and members of the engineering/computer science faculty at Texas A&M to identify candidate therapies for medulloblastoma.

2. RECRUITMENT OF RISING STARS SLATE FY20.7, FY20.8 and FY20.9

Peer Review Recommendations

The applications were evaluated and scored by the Scientific Review Council (SRC) to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Purpose of Recruitment of Rising Stars Awards:

The aim is to recruit outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.

Funding levels for Recruitment of Rising Stars Awards:

Up to \$4 million over a period of 5 years.

Recommended Awards:

Five Recruitment of Rising Stars grant applications were submitted and two were recommended by the Scientific Review Council for an award.

RR200056

Candidate: Veronika Fedirko, Ph.D.

Funding Mechanism: Recruitment of Rising Stars

Applicant Organization: The University of Texas M. D. Anderson Cancer Center

Original Organization of Nominee: Emory University

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.0

Recommended Total Budget Award and Duration: \$4,000,000

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Description:

Veronika Fedirko, Ph.D., a molecular cancer epidemiologist who is currently an associate professor at Emory, is recommended for a Rising Star Award to support her recruitment to M.D. Anderson Cancer Center. She has a strong history of funding from the NCI and other agencies and currently holds an R01focused on the role of antibiotics, proton pump inhibitors use, and the microbiome in colorectal cancer progression. At M.D. Anderson she plans to investigate the interrelationship of diet, microbiome, metabolome, and biomarkers of colorectal cancer risk in diverse populations with the aim of defining preventive strategies and risk stratification.

RR200042

Candidate: Ken Wang, Ph.D.

Funding Mechanism: Recruitment of Rising Stars

Applicant Organization: The University of Texas Southwestern Medical Center

Original Organization of Nominee: Johns Hopkins Medical Institutes

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.7

Recommended Total Budget Award and Duration: \$4,000,000

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Description:

Ken Wang Ph.D., a radiation physicist, is recommended for a Rising Star Award to recruit him to UT Southwestern. He is currently an assistant professor and senior clinical physicist at the Johns Hopkins Medical Institutes. He holds multiple NCI grants and is known for developing applications of imaging guided radiation therapy for experimental use that led to the development of small animal irradiators now in broad use.

3. RECRUITMENT FIRST-TIME TENURE TRACK FACULTY MEMBERS SLATE FY20.7, FY20.8 and FY20.9

Peer Review Recommendations

The applications were evaluated and scored by the Scientific Review Council to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, his/her scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Purpose of First Time Tenure Track Faculty Recruitment

The aim is to recruit and support very promising emerging investigators, pursuing their first faculty appointment in Texas, who can make outstanding contributions to the field of cancer research.

Funding levels for First Time Tenure Track Faculty Members Recruitment Up to \$2 million over a period of up to 5 years.

Recommended Projects:

Fourteen Recruitment of First-Time Tenure Track Faculty Members grant applications were submitted and eight were recommended by the Scientific Review Council for an award. Note application RR200050 was withdrawn by the nominating institution on May 1, 2020; therefore, the PIC considered seven applications from this mechanism.

Below is a listing of the candidates with their associated expertise.

RR200040

Candidate: Eric Van Nostrand, Ph.D.

Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member

Applicant Organization: Baylor College of Medicine

Original Organization of Nominee: University of California, San Diego

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.0

Recommended Total Budget Award and Duration: \$2,000,000.

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas,

Computational biology, and analytic methods.

Description:

Eric Van Nostrand, Ph.D., is recommended for a CPRIT First Time Tenure Track Faculty Member Award to recruit hm to the Baylor College of Medicine from the University of California San Diego. He uses computational and experimental approaches to explore how RNA binding proteins can drive aberrant gene expression and therapeutic vulnerabilities in cancer. He is an outstanding recruit who reviewers noted fulfills all the requirements for a young

investigator to be exceptionally promising: he is highly productive, innovative, a major developer of RNA related technology and is good at getting grants.

RR200039

Candidate: Liela Romero, Ph.D.

Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member

Applicant Organization: Baylor University **Original Organization of Nominee:** MIT

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.2

Recommended Total Budget Award and Duration: \$2,000,000.

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas,

Description:

Liela Romero, Ph.D., is a talented chemist recommended for a CPRIT First Time Tenure Track Faculty Member Award to recruit her to Baylor University from MIT. She plans to develop a selective inhibitor of DNA methylation for clinical use. Her project will have the help of a very strong group of collaborators at Baylor University, UT Southwestern and MD Anderson. CPRIT reviewers noted that these are very strong collaborators with diverse expertise which will strongly support her plans and capitalize on a CPRIT supported state-of-the-art cancer chemistry program in Waco.

RR200045

Candidate: Robert Hillman, M.D., Ph.D.

Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member **Applicant Organization:** The University of Texas M. D. Anderson Cancer Center

Original Organization of Nominee: The University of Texas MD Anderson Cancer Center

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.2

Recommended Total Budget Award and Duration: \$2,000,000.

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas,

Description:

Robert Hillman, M.D., Ph.D., is a surgeon-scientist recommended for a CPRIT First Time Tenure Track Faculty Member Award to retain him at M.D. Anderson. He plans to investigate the genomics of gynecologic cancers, building on research conducted while a fellow with Dr. Futreal, a CPRIT Established Investigator and Chair of Genomic Medicine at M.D. Anderson. He and his mentors have developed a clear plan for the establishment of his independent research career.

RR200065

Candidate: Jason Lee, Ph.D.

Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member

Applicant Organization: Baylor College of Medicine

Original Organization of Nominee: University of Colorado, Boulder

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.8

Recommended Total Budget Award and Duration: \$2,000,000.

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas,

Description:

Jason Lee, Ph.D., is recommended for a CPRIT First Time Tenure Track Faculty Member Award to recruit him to Baylor College of Medicine from the University of Colorado, Boulder. He plans an imaginative research program involving cutting-edge imaging and biochemistry that draws on his unique background in electrical engineering and biochemical training to investigate metastatic breast cancer and inflammation associated with pancreatic cancer. A CPRIT reviewer commented, "This is a top-quality candidate, exciting project and very high-quality overall package. This kind of application is the reason why we enjoy reviewing for CPRIT!"

R200054

Candidate: Megan Whisenant, Ph.D, RN, FNP-BC

Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member Applicant Organization: The University of Texas Health Science Center at Houston Original Organization of Nominee: The University of Texas MD Anderson Cancer Center Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.0

Recommended Total Budget Award and Duration: \$500,000

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas, Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions

Description:

Meagan Whisenant, Ph.D., is recommended for a CPRIT First Time Tenure Track Faculty Member Award to recruit her to the UT Science Center at Houston from M.D. Anderson. Her work focuses on cancer symptom monitoring and management using patient reported outcomes. The Cizik School of Nursing and collaborations with M.D. Anderson oncologists and patients will provide a very strong research environment for the proposed research. The institutional support for the candidate is unusually robust

RR200070

Candidate: Matthew Parker, Ph.D.

Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member **Applicant Organization:** The University of Texas Southwestern Medical Center

Original Organization of Nominee: University of California, Berkeley

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.0

Recommended Total Budget Award and Duration: \$2,000,000.

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas,

Description:

Matthew Parker, Ph.D., a structural biologist, is recommended for a CPRIT First Time Tenure Track Faculty Member Award to recruit him to UT Southwestern from the University of California, Berkley. He plans highly innovative studies of the mechanisms underlying the role of DNA replication proteins and their interaction with the cell cycle machinery. Given the central

role of aberrant DNA replication, DNA repair, and the cell cycle in cancer, it is highly likely that the proposed work will have a very significant impact on cancer research.

RR200059

Candidate: Klementina Fon Tracer, D.V.M., Ph.D.

Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member

Applicant Organization: Texas Tech University

Original Organization of Nominee: St. Jude Children's Research Hospital

Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.2

Recommended Total Budget Award and Duration: \$1,400,000

CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas,

Description:

Klementina Fon Tracer, D.V.M., Ph.D., is recommended for a CPRIT First Time Tenure Track Faculty Member Award to recruit her to Texas Tech University School of Veterinary Medicine from St Jude Children's Research Hospital in Memphis. She obtained her D.V.M. and Ph.D. from the University of Ljubljana in Slovenia followed by a Fulbright Fellowship that supported postdoctoral research at UT Southwestern with David Mangelsdorf. Most recently she has been a research scientist with Dr. Ryan Potts, a CPRIT Scholar now at St Jude. She plans to continue her research begun at St Jude on the functions of the Melanoma Antigen Gene (MAGE) tumorassociated proteins on resistance to stress in both the testis and cancer cells.

Attachment #1

	*Academic Research Program Priorities Addressed by Recommended Awards (*Some grant awards address more than one program priority and are double counted.)									
Scale	Recruitment of outstanding cancer researchers to Texas	A broad range of innovative, investigator-initiated research projects	Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions	Computational biology and analytic methods	Childhood Cancers	Hepatocellular Cancer	Population Disparities			
60,000,000										
50,000,000										
40,000,000	\$41,973,674 13 Awards									
30,000,000										
20,000,000										
10,000,000										
5,000,000				\$2,000,000	\$5,073,674 1 Award	\$6,000,000 1 Award	\$6,000,000 1 Award			
0			\$500,000 1 Award	1 Award						



Attachment #2 RFA Descriptions

• Recruitment of Established Investigators (RFA R-20-1 REI):

Recruits outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.

Award: Up to \$6 million over a period of five years.

• Recruitment of Rising Stars (RFA R-20-1 RRS):

Recruits outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research. Award: Up to \$4 million over a period of five years.

• Recruitment of First-Time Tenure Track Faculty Members (RFA R-20-1. RFT): Supports very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research. Award: Up to \$2 million over a period up to five years.





San Diego

Ludwig Institute for Cancer Research Ltd April 13, 2020

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@health.ucsd.edu

San Diego Branch

UC San Diego School of Medicine CMM-East / Rm 3058 9500 Gilman Dr - MC 0660 La Jolla, CA 92093-0660

T 858 534 7804 **F** 858 534 7750

The Honorable Dee Margo
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to dee@deemargo.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mayor Margo and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on February 13, 2020 (REC Cycle 20.7), March 12, 2020 (REC Cycle 20.8) and on April 9, 2020 (REC Cycle 20.9) to review the applications submitted to CPRIT under the Recruitment of Established Investigators, Recruitment of Rising Stars and Recruitment of First-Time Tenure Track Faculty Members.

The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation scores are stated for each grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is \$43,973,674.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research and exceptional potential for achieving future impact in basic, translational, population based or clinical research.

Sincerely yours,

Richard D. Kolodner

Attachment

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Rank	App ID	Mechanism	Candidate	Organization	Budget	Overall Score
1	RR200040	RFTFM	Van Nostrand, Eric	Baylor College of Medicine	\$2,000,000	1.0
2	RR200050	RFTFM	Cao, Junyue	Baylor College of Medicine	\$2,000,000	1.0
3	RR200039	RFTFM	Romero, Liela	Baylor University	\$2,000,000	1.2
4	RR200045	RFTFM	Hillman, Robert	The University of Texas M. D. Anderson Cancer Center	\$2,000,000	1.2
5	RR200057	REI	Felsher, Dean	The University of Texas M. D. Anderson Cancer Center	\$6,000,000	1.2
6	RR200072	REI	Wei, Wenyi	The University of Texas Southwestern Medical Center	\$6,000,000	1.5
7	RR200065	RFTFM	Lee, Jason	Baylor College of Medicine	\$2,000,000	1.8
8	RR200046	REI	Manning, Henry Charles	The University of Texas M. D. Anderson Cancer Center	\$5,000,000	2.0
9	RR200056	RRS	Fedirko, Veronika	The University of Texas M. D. Anderson Cancer Center	\$4,000,000	2.0
10	RR200054	RFTFM	Whisenant, Megan	The University of Texas Health Science Center at Houston	\$500,000	2.0
11	RR200070	RFTFM	Parker, Matthew	The University of Texas Southwestern Medical Center	\$2,000,000	2.0
12	RR200059	RFTFM	Fon Tracer, Klementina	Texas Tech University	\$1,400,000	2.2
13	RR200042	RRS	Wang, Ken	The University of Texas Southwestern Medical Center	\$4,000,000	2.7
14	RR200043	REI	Lele, Tanmay	Texas A&M Engineering Experiment Station	\$5,073,674	2.8

REI- Recruitment of Established Investigators RRS- Recruitment of Rising Stars RFTFM- Recruitment of First-Time, Tenure Track Faculty Members



MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS

From: CINDY WALKERPEACH, PHD

CHIEF PRODUCT DEVELOPMENT OFFICER

Subject: ADDITIONAL FY 20.1 PRODUCT DEVELOPMENT GRANT

RECOMMENDATION

Date: MAY 5, 2020

Summary of Recommendation:

The Product Development Review Council (PDRC) and the Program Integration Committee (PIC) recommend the Oversight Committee approve a Product Development Research grant award for the following applicant: Invectys USA, Inc. Table 1 reflects information regarding the award recommendation, including the maximum recommended funding amount and the evaluation score for the single grant application proposed for award.

The single application recommended by the PDRC and the PIC is an application for which the PDRC had taken "No Action" at its January 13, 2020, Diligence Meeting (Product Development Cycle 20.1), pending review of additional information requested from the applicant. The applicant provided additional information as requested, which was reviewed by the PDRC at the March 17, 2020, Diligence Meeting. As a result of the March 17, 2020, Diligence Meeting, the PDRC recommended approval of an award for applicant Invectys USA, Inc.

The PDRC and the PIC did not make any changes to the proposed goals and objectives, timeline or budget for the single applicant recommended for funding. In addition, the PDRC and the PIC did not identify any specific issues or contingencies for the company to address prior to contract execution.

Table 1: Additional PDRC Award Recommendation for 20.1 Review Cycle

Rank	Application	Mechanism	Company	Project	Maximum	Overall
	ID	(Cycle)	Name		Recommended	Score*
					Budget	
1	DP200034	RELCO	Invectys	CARGo: a CAR-T cell program	\$14,196,990	3.3
		(20.1)	USA	targeting HLA-G - a novel immune		
			Inc.	checkpoint and tumor specific		
				antigen for advanced clear cell		
				renal and ovarian carcinomas		
				Total	\$14,196,990	

^{*} average reviewer score from in-person peer review

Background - Product Development FY 2020 Review Cycle 1

CPRIT received forty-two (42) applications for the Product Development FY 2020 Award Cycle 1 by the August 7, 2019, deadline. Two (2) applicants were administratively withdrawn, leaving forty (40) applications for initial evaluation by the peer reviewers. After peer review and in-person presentations by the applicants, the PDRC convened on January 13 to conduct the due diligence review meeting for seven (7) applications from the 20.1 cycle.

After consideration of the diligence materials, the PDRC recommended four (4) of the 20.1 applications for grant awards and one applicant as "No Action" pending additional information from the applicant. At the February 19, 2020 meeting, the Oversight Committee approved four (4) seed awards, one each to Asylia Therapeutics, Inc. (\$3,000,000), Dialectic Therapeutics, Inc. (\$3,000,000), Texas Magnetic Imaging Technology, Inc. (\$2,997,384), and Barricade Therapeutics, Corp. (\$2,999,376). Total funding for the four (4) seed awards was \$11,996,760.

The "No Action" applicant provided additional information as requested, which was reviewed by the PDRC at the March 17, 2020, Diligence Meeting. As a result of the March 17, 2020, Diligence Meeting, the PDRC recommended approval of an award for applicant Invectys USA Inc. (Table 1).

Dr. Jack Geltosky, Chair PDRC, noted in his letter to the PIC and the Oversight Committees that the PDRC's recommendation to fund the single recommended award reflected 50+ hours of individual review and panel discussion of the proposal as well as the PDRC's review of the diligence materials for the company.

The PIC convened on May 5, 2020 and recommended the PDRC's additional proposed award, for the 20.1 cycle, to the Oversight Committee.

Program Priorities Addressed by the Additional Proposed Award for Cycle 20.1

The chart below reflects the single recommended application addresses one or more of the Product Development Research Program priorities.

Applications Addressing Priorities*	Product Development Program Priorities	Award Amount per Priority*
1	Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies	\$14,196,990
1	Funding projects addressing large or challenging unmet medical needs	\$14,196,990
1	Investing in early stage projects where private capital is least available	\$14,196,990

0	Stimulating commercialization of technologies developed at Texas institutions	\$0
1	Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations	\$14,196,990
1	Providing appropriate return on taxpayer investment	\$14,196,990

^{*}The proposed grant award addresses more than one program priority.

Mechanism of Support and Program Objectives

Proposals submitted in the 20.1 review cycle responded to one of three product development research RFAs.

• Texas Company Product Development Research Award (TEXCO)

This award mechanism seeks to support early stage "startup" and established companies in the development of innovative products and services with significant potential impact on cancer patient care. The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Companies must be headquartered in Texas.

Strong candidates for the TXCO award have developed a sufficiently robust data package, value proposition, regulatory strategy, manufacturing plan, and experienced business/management team to warrant the amount of funding requested.

Award: Maximum amount \$20 million over 36 months

• Relocation Company Product Development Research Award (RELCO)

This award mechanism seeks to support early stage "startup" and established companies in the development of innovative products and services with significant potential impact on cancer patient care. The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Companies must relocate to Texas upon receipt of award.

Strong candidates for the RELCO award have developed a sufficiently robust data package, value proposition, regulatory strategy, manufacturing plan, and experienced business/management team to warrant the amount of funding requested.

Award: Maximum amount \$20 million over 36 months

• Seed Award for Product Development Research (SEED)

This award mechanism seeks to support early stage "startup" companies in the development of innovative products and services with significant potential impact on cancer patient care.

The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Company applicants must be headquartered in Texas or be willing to relocate to Texas upon receipt of award

Strong candidates for the SEED award have developed compelling discovery stage data and/or developed a working prototype (if applicable) around a novel compound, diagnostic, device, computational tool, etc. that warrants further development efforts to establish proof of concept (POC) on the early pathway to commercial product. In addition, strong candidates have at a minimum developed a strong value proposition, preliminary regulatory strategy, preliminary manufacturing plan, and early business/management team to warrant the amount of funding requested.

Award: Maximum amount of \$3 million over 36 months.

CPRIT's Grant Award Contract and Risk Mitigation

Investing in early stage translational cancer research is inherently risky. Products in development at CPRIT Product Development Research awardees that show promise in the laboratory and in animal studies may not make a measurable difference in humans or the treatment's side effects may be so severe as to not justify the benefits. Along with the increased risk of technical failure, human studies are more complex and expensive than laboratory and animal studies.

CPRIT addresses the risk associated with product development research awards by tying disbursement of grant funds to the grantee achieving specific project goals and objectives. The grant contract requires the company to report at least annually on its progress. To receive the next tranche of project funding, the grantee must show that it has accomplished all the goals and objectives for the previous project year. The company will only receive the entire approved award amount if it successfully achieves all project goals and objectives. Because contractual goals are usually associated with project milestones, such as receiving FDA approval for an Investigational New Drug filing or completing a clinical trial, achieving all agreed-upon goals also means that the project is making meaningful progress to becoming a treatment option.

Product Development Research Program Award Recommendation by the PDRC and PIC FY 2020 Review Cycle 1

Invectys USA Inc. Proposed Company Relocation Product Development Research Award

Summary of Recommendation

The PDRC and the PIC recommend the Oversight Committee approve a Company Relocation Product Development Research award to Invectys USA Inc. for \$14,196,990.

Invectys USA Inc. is developing a novel human leukocyte antigen G (HLA-G) CAR-T platform for the treatment of solid tumors that have been shown to be resistant to immunotherapy. The Invectys approach is to reprogram immune cells to become killer cells for any tumor cells that express HLA-G. This would potentially increase responsiveness to immunotherapy in many cancer patients. If this application is recommended for funding, the company would relocate to Texas from Paris, France.

CPRIT Product Development Research Program Priorities Addressed

Invectys USA Inc.'s proposed project addresses five of the six Product Development Research Program Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early stage projects where private capital is least available;
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale

Invectys USA Inc. has proposed to use CPRIT funding to conduct early clinical studies to advance its novel CAR-T platform. The proposed Invectys project is focused on the HLA-G molecule, a powerful modulator of the human immune system. HLA-G protects the fetus from the mother's immune system. However, in cancer tumors, cells are selected that express HLA-G to protect the tumor from attacks of the immune system. There are very few cell surface molecules that are so specific, and by comparison, current targets in immunotherapy are far less specific.

Cellular immunotherapy is a powerful new weapon in the anti-cancer arsenal, and the research community has made rapid progress in this area. However, only a small percentage of patients respond. The Invectys approach is to reprograms immune cells to become killer cells for any tumor cells that express HLA-G. This would potentially increase responsiveness to immunotherapy in many cancer patients.

Select Reviewer Comments

- Target well-validated by prestigious laboratory as the basis for founding the company, and biology established across multiple laboratories.
- The development proposal appears scientifically sound and next steps are appropriate given the still relative early stage of the project.
- The Board and current investors have agreed to provide a 1:1 match to any CPRIT funding which puts this proposal in a very favorable position from the perspective of funding. In addition, since its inception in 2010, the company has successfully raised >\$40M which establishes a certain track record of success.
- Development of this CAR-T cell treatment targeting HLA-G on cancer cells and in the microenvironment around these cells could be very profitable. It is possible that this could be used for not only solid tumors but also heme cancers, which would be a broad application.
- This is a well written application seeking funding to pursue a high value & high interest cellular therapeutic approach against a novel target in that space which would significantly advance the field of cellular therapy.

diagnostics not challenging unmet pri		Investing in early stage projects when private capital is least available	Stimulating commercialization of technologies developed at Texas institutions	Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life sciences expertise, especially C-level staff to lead seed clusters of life science expertise at various Texas locations	Providing appropriate return on Texas taxpayer investment
\$14,196,990 1 project	\$14,196,990 1 project	\$14,196,990 1 project	\$0 0 projects	\$14,196,990 1 project	\$14,196,990 1 project
• DP200034	• DP200034	• DP200034		• DP200034	• DP200034

April 20, 2020

Donald "Dee" Margo
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to dee@deemargo.com
Via email to Dee Margo's assistant, Olivia Zepeda: ozepeda@deemargo.com

Wayne R. Roberts
Program Integration Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Dee and Wayne,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for one (1) application from CPRIT's Product Development Research 20.1 grant award cycle. The PDRC convened on March 17, 2020 and recommends that the Program Integration Committee and the Oversight Committee approve a Product Development Research grant award for the following applicants: Invectys USA Inc.

The one (1) application for recommendation by the PDRC is an application for which the PDRC had taken "No Action" at its January 13, 2020 Diligence Meeting (Product Development Cycle 20.1), pending review of additional information requested from the applicant. The applicant provided additional information as requested, which was reviewed by the PDRC at the March 17, 2020, Diligence Meeting. As a result of the March 17, 2020, Diligence Meeting, the PDRC recommended to approve an award for applicant Invectys USA Inc.

The PDRC did not make any changes to the proposed goals and objectives, timeline or budget for the one applicant recommended for funding.

The application included in the PDRC's recommendation reflects 50+ hours of individual review and panel discussion of the applicant's proposal as well as the PDRC's review of the due diligence report. Our recommendation is consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

Sincerely,

Jack Geltosky, PhD

Ase tousky

Chair, CPRIT Product Development Review Council

Attachment

Product Development Review Council Award Recommendations

FY 2020 Cycle 1

Rank	Application ID	Mechanism (Cycle)	Company Name	Project	Maximum Recommended Budget	Overall Score*
1	DP200034	RELCO (20.1)	Invectys USA Inc.	CARGo: a CAR-T cell program targeting HLA-G - a novel immune checkpoint and tumor specific antigen for advanced clear cell renal and ovarian carcinomas	\$14,196,990	3.3
				Total	\$14,196,990	

^{*} average reviewer score from in-person peer review



May 13, 2020

Oversight Committee Members,

Pursuant to 25 T.A.C. § 703.7(j), I request that the Oversight Committee approve authority for CPRIT to advance grant funds upon execution of a grant contract for the company that the Oversight Committee will consider for a product development grant award at its May 20, 2020, meeting. The Program Integration Committee has recommended the company for a grant award.

Although CPRIT disburses most grant funds pursuant to requests for reimbursement, CPRIT may disburse grant funds in advance payments consistent with the General Appropriations Act, Article IX, § 4.03(a). Typically, the grant amount that CPRIT advances is based upon the project year budget or tranche amount. All grant recipients, including those that receive advance payment of grant funds, must submit quarterly financial status reports that CPRIT's financial staff reviews and approves. The product development grant recipients must also certify that they have matching funds available to invest in the project prior to any disbursement of funds. Failure to submit the financial status reports on a timely basis or to certify matching funds will result in forfeiture of reimbursement for expenses for the quarter and may result in grant termination and repayment of grant funds.

Advance payment of grant funds is necessary because the projects proposed for grant awards involve preclinical work and/or clinical trials. The cost structure for this type of work is highly front loaded and service providers require substantial upfront payments. Advancing grant funds allows these projects to begin work as quickly as possible.

Sincerely,

Wayne Roberts

CPRIT Chief Executive Officer



May 6, 2020

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendations for funding 14 grant applications totaling \$56,170,664. The PIC recommendations for 13 academic research grant awards and one product development research grant award are attached.

Dr. Jim Willson, CPRIT's Chief Scientific Officer and Dr. Cindy WalkerPeach, CPRIT's Chief Product Development Officer, have prepared overviews of the academic research and product development research slates to assist your evaluation of the recommended awards. The overviews are intended to provide a comprehensive summary with enough detail to understand the substance of the proposal and the reasons endorsing grant funding. In addition to the full overviews, all of the information considered by the Review Councils is available by clicking on the appropriate link in the portal. This information includes the application, peer reviewer critiques, and the CEO affidavit for each proposal.

The approval of these grant recommendations is governed by a statutory process that requires two-thirds of the members present and voting to approve each recommendation. Vince Burgess, CPRIT's Chief Compliance Officer, will certify that the review process for the recommended grants followed CPRIT's award process prior to any Oversight Committee action.

The award recommendations will not be considered final until the Oversight Committee meeting on May 20, 2020. Consistent with the non-disclosure agreement that all Oversight Committee members have signed, the recommendations should be kept confidential and not be disclosed to anyone until the award list is publicly announced at the Oversight Committee meeting. I request that Oversight Committee members not print, email or save to your computer's hard drive any material on the portal. I appreciate your assistance in taking all necessary precautions to protect this information.

If you have any questions or would like more information on the review process or any of the projects recommended for an award, CPRIT's staff, including myself, Dr. Willson, and Dr. WalkerPeach are always available. Please feel free to contact us directly should you have any questions. The programs that will be supported by the CPRIT awards are an important step in our efforts to mitigate the effects of cancer in Texas.

Thank you for being part of this endeavor.

Sincerely, Wayne R. Roberts, Chief Executive Officer

Academic Research Award Recommendations -

The PIC unanimously recommends approval of 13 academic research grant proposals totaling \$41,973,674. The recommended grant proposals were submitted in response to three grant mechanisms: *Recruitment of First-Time, Tenure-Track Faculty Members; Recruitment of Established Investigators*, and *Recruitment of Rising Stars*. The Scientific Review Council provided the prioritized list of recommendations for the awards to the presiding officers on April 13, 2020. The PIC approved the recommended rank order as presented by the Scientific Review Council except for RR200050, which was not considered by the PIC because the application was withdrawn by the applicant prior to the PIC meeting.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these academic research proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- strengthen and enhance fundamental science in cancer research;
- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- have a demonstrable economic development benefit to this state;
- enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources; and
- address the goals of the Texas Cancer Plan.

Academic Research Recruitment Grant Award Recommendations

Rank	Application ID	Award Mechanism	Score	Candidate	Organization	Budget
1	RR200040	RFTFM	1.0	Van Nostrand, Eric	Baylor College of Medicine	\$2,000,000
2	RR200039	RFTFM	1.2	Romero, Liela	Baylor University	\$2,000,000
3	RR200045	RFTFM	1.2	Hillman, Robert	The University of Texas M. D. Anderson Cancer Center	\$2,000,000
4	RR200057	REI	1.2	Felsher, Dean	The University of Texas M. D. Anderson Cancer Center	\$6,000,000
5	RR200072	REI	1.5	Wei, Wenyi	The University of Texas Southwestern Medical Center	\$6,000,000
6	RR200065	RFTFM	1.8	Lee, Jason	Baylor College of Medicine	\$2,000,000
7	RR200046	REI	2.0	Manning, Henry Charles	The University of Texas M. D. Anderson Cancer Center	\$5,000,000
8	RR200056	RRS	2.0	Fedirko, Veronika	The University of Texas M. D. Anderson Cancer Center	\$4,000,000
9	RR200054	RFTFM	2.0	Whisenant, Megan	The University of Texas Health Science Center at Houston	\$500,000
10	RR200070	RFTFM	2.0	Parker, Matthew	The University of Texas Southwestern Medical Center	\$2,000,000
11	RR200059	RFTFM	2.2	Fon Tracer, Klementina	Texas Tech University	\$1,400,000
12	RR200042	RRS	2.7	Wang, Ken	The University of Texas Southwestern Medical Center	\$4,000,000
13	RR200043	REI	2.8	Lele, Tanmay	Texas A&M Engineering Experiment Station	\$5,073,674

REI: Recruitment of Established Investigators
RFTFM: Recruitment of First-Time, Tenure-Track Faculty Members

RRS: Recruitment of Rising Stars

Product Development Research Award Recommendations -

The PIC unanimously recommends approval of one product development research grant proposal totaling \$14,196,990. The recommended grant proposal was submitted in response to following request for applications: *Company Relocation Product Development Research Awards*. The Product Development Review Council provided its recommendation to the presiding officers on April 20, 2020. The PIC approved the recommended rank order as presented by the Product Development Review Council.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that this product development research proposal met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- strengthen and enhance fundamental science in cancer research;
- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- are interdisciplinary or interinstitutional;
- are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;
- have a demonstrable economic development benefit to this state;
- expedite innovation and commercialization, attract, create, or expand private sector entities that will
 drive a substantial increase in high-quality jobs, and increase higher education applied science or
 Technology research capabilities; and
- address the goals of the Texas Cancer Plan.

Product Development Research Grant Award Recommendation

Rank	Application ID	Mechanism	Score	Company	Project	Recommended Budget
1	DP200034	RELCO	3.3	Invectys USA Inc.	CARGo: a CAR-T cell program targeting HLA-G - a novel immune checkpoint and tumor specific antigen for advanced clear cell renal and ovarian carcinomas	\$14,196,990

RELCO: Company Relocation Product Development Research Awards



MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: VINCE BURGESS, CHIEF COMPLIANCE OFFICER

SUBJECT: COMPLIANCE CERTIFICATION – MAY 2020 AWARDS

DATE: MAY 5, 2020

Summary and Recommendation:

As CPRIT's Chief Compliance Officer, I am responsible for reporting to the Oversight Committee regarding the agency's compliance with applicable statutory and administrative rule requirements during the grant review process. I have reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the:

- Recruitment of Established Investigators
- Recruitment of Rising Stars
- Recruitment of First-Time, Tenure-Track Faculty Members
- Company Relocation Product Development Research Awards

I have conferred with staff at CPRIT and General Dynamics Information Technology (GDIT), CPRIT's contracted third-party grants administrator, regarding the academic research awards and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. I am satisfied that the application review process that resulted in the above mechanisms recommended by the Program Integration Committee (PIC) followed applicable laws and agency administrative rules. I certify the academic research and product development research award recommendations for the Oversight Committee's consideration.

I note that on January 13, 2020, the Product Development Review Council (PDRC) considered seven applications from cycle 20.1, recommended four Seed award applications to the PIC, and took no action on one application from the Company Relocation Product Development Research Awards mechanism. The no action decision reflected the PDRC's need for additional information from the applicant prior to making a final award recommendation. The PDRC considered the application again at its March 17, 2020, meeting and recommended it to the PIC for the May 5, 2020 meeting. The Company Relocation award recommendation is the subject of this certification, which includes some information originally from my February certification.

Background:

CPRIT's Chief Compliance Officer must report to the Oversight Committee regarding compliance with the statute and the agency's administrative rules. Among the Chief Compliance Officer's responsibilities is the obligation "to ensure that all grant proposals comply with this chapter and rules adopted under this chapter before the proposals are submitted to the oversight committee for approval." Texas Health & Safety Code § 102.051(c) and (d).

CPRIT uses a compliance pedigree process to formally document compliance for the grant award process. The compliance pedigree tracks the grant application as it moves through the review process and documents compliance with applicable laws and administrative rules. A compliance pedigree is created for each application; the information related to the procedural steps listed on the pedigree is entered and attested to by GDIT employees and CPRIT employees. CPRIT relies on GDIT to accurately record a majority of the information on the pedigree from the pre-receipt stage to final Review Council recommendation. To the greatest extent possible, information reported in the compliance pedigree is imported directly from data contained in CPRIT's Application Receipt System (CARS), the grant application database managed by GDIT. This is done to minimize the opportunity for error caused by manual data entry.

No Prohibited Donations:

Although CPRIT is statutorily authorized to accept gifts and grants pursuant to Texas Health & Safety Code § 102.054, the statute prohibits CPRIT from awarding a grant to an applicant who has made a gift or grant to CPRIT or a nonprofit organization established to provide support to CPRIT. I note that Texas Health & Safety Code § 102.251(a)(3) specifically addresses "donors from any nonprofit organization established to provide support to the institute compiled from information made available under § 102.262(c)." To the best of my knowledge, there are no nonprofit organizations that have been established to provide support to CPRIT on or after June 14, 2013, the effective date of this statutory change. The only nonprofit organization established to provide support to the Institute was the CPRIT Foundation; however, the CPRIT Foundation ceased operations and changed its name and its purpose prior to June 14, 2013. The institute has received no donations from the CPRIT Foundation made on or after June 14, 2013.

I have reviewed the list of donors to CPRIT maintained by CPRIT (and listed on CPRIT's website) and compared the donors to the list of applicants. No donors to CPRIT have submitted applications for grant awards during the award cycles that are the subject of this report.

Pre-Receipt Compliance:

The activities listed on a compliance pedigree in the pre-receipt stage cover the period beginning with CPRIT's approval and issuance of the Request for Applications (RFA) through the submission of grant applications. For the period covering these RFAs, CPRIT published the

RFAs on the Texas.gov eGrants website. The RFA specifies a deadline and mandates that only those applications submitted electronically through CPRIT's Application Receipt System (CARS) are eligible for consideration. CARS blocks an application from being submitted once the deadline passes. Occasionally, an applicant may have technical difficulties that prevent the applicant from completing the application submission. When this occurs, the applicant may appeal to CPRIT (through the CPRIT Helpdesk that is managed by GDIT) to allow for a submission after the deadline. The program officer considers any requests for extension and may approve an extension for good cause. When a late filing request is approved, the applicant is notified and CARS is reopened for a brief period – usually two to three hours – the next business day.

Academic Research:

For recruitment Cycles 20.7, 20.8 and 20.9, eight applications were received for the Recruitment of Established Investigators RFA, five applications were received for the Recruitment of Rising Stars RFA, and 19 applications were received in response to the Recruitment of First-Time, Tenure Track Faculty members RFA.

All Academic Research RFAs were posted on the Texas.gov eGrants website and all applications were submitted through CARS.

Product Development Research:

For Cycle 20.1, eight applications were received for the Texas Company Product Development Awards RFA, 16 applications were received for the Company Relocation Product Development Research Awards RFA, and 18 applications were received for the Seed Awards for Product Development Research RFA.

All product development research RFAs were posted on the Texas.gov eGrants website and all applications were submitted through CARS. One applicant requested an extension to submit an application after the deadline. The program officer determined that there was good cause for the request and the deadline was extended.

Receipt, Referral, and Assignment Compliance:

Once applications have been submitted through CARS, GDIT staff reviews the applications for compliance with RFA directions. If an applicant does not comply with the directions, GDIT notifies the program officer and the program officer makes the final decision whether to administratively withdraw the application. Recruitment grant applications and the Dissemination of CPRIT-funded Cancer Control Intervention grant applications are assigned to their respective review council members for review. All other academic research, product development research, and prevention applications are assigned by the peer review panel chair to their respective peer review panels. Prior

to distribution of the applications, reviewers are given summary information about the applicant, including the Project Director and collaborators. Reviewers must sign a conflict of interest agreement and confirm that they do not have a conflict of interest with the application before they are provided with the full application.

The pedigrees attest that a conflict of interest statement was signed by each primary reviewer for each Grant Application.

Academic Research:

For Cycles 20.7, 20.8 and 20.9, two recruitment application were withdrawn by the applicant prior to the Scientific Review Council and one recruitment application was withdrawn by the applicant after the Scientific Review Council, but before the Program Integration Committee meeting.

Product Development Research:

Three applications were withdrawn prior to peer review; two applications were administratively withdrawn and one application was withdrawn by the applicant.

Peer Review:

Primary reviewers (typically three) must submit written critiques for each of their assigned applications prior to the peer review meeting. After the peer review meetings, a final score report from the review committee is delivered to the Review Council for additional review. Following the peer review meeting, each participating peer reviewer must sign a post-review peer review statement certifying that the reviewer knew of and understood CPRIT's conflict of interest policy and followed the policy for this review process.

Academic Research:

For the Recruitment Awards, the applications are reviewed by the Scientific Review Council (SRC), which assigns two members of the SRC to be primary reviewers. I reviewed the supporting documentation, such as the sign-out sheets, third-party observer reports, and post-review peer reviewer statements. Sign out sheets are used to document when a reviewer with a conflict of interest associated with a particular application leaves the room (or disengages from the conference call) during the discussion and scoring of the application. For Cycles 20.7, 20.8 and 20.9, four conflicts of interest were declared by the SRC.

I reviewed and confirmed that the post review conflict of interest statements were signed by the SRC members that attended the Recruitment Review Panel meetings on February 13, March 12, and April 9, 2020.

Product Development Research:

Product Development Research awards go through a peer review teleconference screening call to determine which applications will be invited to in-person review. Those applicants that attend in-person review are once again evaluated by peer reviewers. Applicants recommended after in-person review must then go through operations and management due diligence review, which is conducted by outside contractors and outside intellectual property counsel. The Product Development Review Council (PDRC) recommends awards after due diligence to the PIC. I have verified from GDIT documentation and the third-party observer reports that those reviewers with conflicts did not participate in review of applications for which they indicated a conflict of interest. All declared COIs left the room or disengaged from the conference call and did not participate in the discussion of relevant applications.

I reviewed and confirmed that the post review conflict of interest statements were signed by peer review members for each panel as well as the six PDRC members and eight expert reviewers that attended the Due Diligence meeting on January 13, 2020 and the six PDCR members that attended the Due Diligence meeting on March 17, 2020.

Programmatic Review:

Programmatic review is conducted by the Scientific Review Council, Prevention Review Council, and Product Development Review Council for their respective awards. Each review council creates a final list of grant applications it will recommend to the PIC for grant award slates.

Academic Research:

I reviewed the third-party observer reports for each Review Council meeting. The third-party observer reports document that the Review Council discussions were limited to the merits of the applications and established evaluation criteria and that conflicted reviewers, if applicable, exited the room or the conference call when the application was discussed.

I reviewed and confirmed that the Review Council recommendations corresponded to RFAs that had been released. I also confirmed that the pedigrees reflect the date of the Review Council meeting and that the applications were recommended by the Review Council.

Because recruitment applications are assigned to the SRC, programmatic and peer review occur simultaneously when applications are reviewed by the SRC.

<u>Product Development Research:</u>

For Cycle 20.1, seven applications went through due diligence and four of those applications were recommended by the PDRC to the PIC at the Due Diligence Meeting on January 13, 2020. These four applications were approved for funding by the Oversight Committee at the February 2020 meeting. The PDRC took no action on one application from the Company Relocation mechanism at the January 17, 2020, meeting. The decision reflected the PDRC's need for

additional information form the applicant prior to making a final award recommendation. The PDRC considered the application again at its March 17, 2020, meeting and recommended the application to the PIC. Additionally, the PDRC recommended this award rather than another application in this mechanism with a better score. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio.

I note that on November 18, 2019, Mr. Roberts, CPRIT's Chief Executive Officer, granted members of the PDRC a waiver from the general prohibition against communicating with grant applicants, pursuant to Texas Administrative Code § 702.19(e). A copy of the waiver is included in the "CEO Affidavit-Supporting Information" Company Relocation Product Development Research Awards packet.

Program Integration Committee (PIC) Review:

Texas Health & Safety Code § 102.051(d) requires the Chief Compliance Officer to attend and observe the PIC meetings to ensure compliance with CPRIT's statute and administrative rules. CPRIT's statute requires that, at the time the PIC's final Grant Award recommendations are formally submitted to the Oversight Committee, the Chief Executive Officer shall prepare a written affidavit for each Grant Application recommended by the PIC containing relevant information related to the Grant Application recommendations.

I attended the May 5, 2020, PIC meeting held via videoconferencing as an observer and confirm that the PIC review process complied with CPRIT's statute and administrative rules. I note that Dr. Hellerstedt was not present at the PIC meeting. The PIC considered 14 applications, and all 14 applications were recommended to move forward to the Oversight Committee. A review of the CEO affidavits confirms that such affidavits were executed and provided for each Grant Application recommendation.



CEO Affidavit Supporting Information

FY 2020 Cycle 1
Company Relocation Product Development
Research Awards

Request for Applications



REQUEST FOR APPLICATIONS RFA C-20.2-RELCO

Company Relocation Product Development Research Awards

Please also refer to the Instructions for Applicants document, which will be posted on December 4, 2019

Application Receipt Opening Date: December 4, 2019 **Application Receipt Closing Date:** January 29, 2020

FY 2020

Fiscal Year Award Period September 1, 2019-August 31, 2020

TABLE OF CONTENTS

1.	KE	Y POINTS	4
2.		OUT CPRIT	
	2.1.	PRODUCT DEVELOPMENT RESEARCH PROGRAM PRIORITIES	
3.	EX	ECUTIVE SUMMARY	6
4.	ME	CHANISM OF SUPPORT	7
5.	OB	JECTIVES	7
6.	FU	NDING INFORMATION	8
7.	KE	Y DATES	9
8.	EL	IGIBILITY	10
	8.1.	APPLICANTS	10
	8.2.	RESUBMISSION POLICY	12
9.	AP	PLICATION REVIEW	13
	9.1.	OVERVIEW	13
	9.2.	REVIEW PROCESS	14
	9.2.		
	9.3.	REVIEW CRITERIA	
	9.3.		
	9.3.2		
10		BMISSION GUIDELINES	
	10.1.		
	10.2.	SUBMISSION DEADLINE EXTENSION	
	10.3.	PRODUCT DEVELOPMENT REVIEW FEE	
	10.4.	APPLICATION COMPONENTS	
		1.1. Layperson's Summary (1,500-character maximum)	
		1.2. Abstract and Significance (5,000-character maximum)	
		4.4. Timeline (1-page maximum)	
		4.5. Slide Presentation (10-page maximum)	
		!.6. Resubmission Summary (1-page maximum)	
		7.7. Development Plan (12-page maximum)	
	10.4	9.8. Business Plan	24
	10.4	9.9. Biographical Sketches of Key Scientific Personnel (8-page maximum)	26
		1.10.Relocation Commitment to Texas (1-page maximum)	
		!.11.Budget	
11		ARD ADMINISTRATION	
12		QUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	
13		NTACT INFORMATION	
	13.1.	HELPDESK	
	13.2.	PROGRAMMATIC QUESTIONS	
14		PENDIX	
		LEVIEWER EVALUATION GUIDELINES FOR THERAPEUTICS	
	14.2 R	LEVIEWER EVALUATION GUIDELINES FOR MEDICAL DEVICES AND DIAGNOSTICS	38

RFA VERSION HISTORY

11/20/2019 RFA release Rev

1. KEY POINTS

This Company Relocation Product Development Research Award mechanism is governed by the following guidelines:

- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools. Products must diagnose cancer, treat cancer, or treat sequelae specific to cancer.
- For therapeutics, Product Development Research award funding supports preclinical research and early clinical research necessary to demonstrate initial clinical safety and efficacy (typically phase 1, phase 2A).
- Recipient companies must commit to be Texas based (see <u>section 8.1</u>). The Cancer
 Prevention and Research Institute of Texas (CPRIT) requires the use of Texas-based
 subcontractors and suppliers unless adequate justification is provided for the use of outof-state entities.
- CPRIT requires recipient companies to raise a portion of the total project budget from external sources. For a company receiving an initial CPRIT award, CPRIT will contribute \$2.00 for every \$1.00 contributed in matching funds by the recipient company. CPRIT reserves the right to seek a higher matching funds contribution (ie, CPRIT will contribute \$1.00 for every \$1.00 contributed in matching funds by the company) from a company that has already received a CPRIT award and is approved for a second award. The demonstration of available matching funds must be made prior to the distribution of CPRIT grant funds, not at the time the application is submitted. CPRIT funds should, whenever possible, be spent in Texas. A company's matching funds must be dedicated to the CPRIT-funded project but may be spent outside of Texas.
- Applicants may request up to \$20 million in CPRIT funds. CPRIT receives many more applications each year than available funds can support. While all requests for funding must be well justified, a funding request at or near the maximum amount will be heavily scrutinized. Such a request must be exceptionally well justified to warrant dedicating a large percentage of CPRIT's product development research budget to the applicant's project.
- Funding will be tranched and tied to the achievement of contract-specified milestones.

- All award contracts include a revenue-sharing agreement. A copy of the revenue-sharing agreement can be found at www.cprit.texas.gov in the Product Development Research Program section. Other contract provisions are specified in CPRIT's Administrative Rules, which are also available at www.cprit.texas.gov.
- An application last submitted but not funded (including resubmission) before December 22, 2017), may be submitted as a new application, even if it was previously resubmitted (see section 8.2).
- Applicant companies are limited to 1 submission per cycle across all CPRIT Product Development award mechanisms.

2. ABOUT CPRIT

The State of Texas established CPRIT, which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the
 development and coordination of effective and efficient statewide public and private
 policies, programs, and services related to cancer and by encouraging cooperative,
 comprehensive, and complementary planning among the public, private, and volunteer
 sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2.1. Product Development Research Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide

transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Product Development Research Program's principles and priorities will also guide CPRIT staff and the Product Development Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Moving forward the development of commercial products to diagnose and treat cancer and improve the lives of patients with cancer
- Creation of good, high-paying jobs for Texans
- Sound financial return on the monies invested
- Development of the Texas high-tech life sciences business environment

Product Development Research Program Priorities

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available; ie, disruptive technologies
- Funding projects addressing large or challenging unmet medical needs
- Investing in early-stage projects when private capital is least available
- Stimulating commercialization of technologies developed at Texas institutions
- Supporting new company formation in Texas or attracting promising companies to
 Texas that will recruit staff with life science expertise, especially experienced C-level
 staff, to lead to seed clusters of life science expertise at various Texas locations
- Providing appropriate return on Texas taxpayer investment

A full description of CPRIT's program priorities may be found at http://priorities.cprit.texas.gov/.

3. EXECUTIVE SUMMARY

CPRIT will foster cancer research as well as product and service development in Texas by providing financial support for a wide variety of projects relevant to cancer. This RFA solicits applications for the research and development of innovative products addressing critically important needs related to diagnosis, prevention, and/or treatment of cancer and the product

development infrastructure needed to support these efforts. CPRIT encourages applicants who seek to apply or develop state-of-the-art products, services (eg, contract research organization services), technologies, tools, and/or resources for cancer research, prevention, or treatment. The award mechanism described in this RFA is designed to encourage the relocation of existing oncology-focused companies or a substantial portion of their business to Texas. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure. The overall goal of this award program is to improve outcomes of patients with cancer by accelerating the development of groundbreaking therapeutics, diagnostics, and tools with a primary focus on Texas-centric programs.

4. MECHANISM OF SUPPORT

The goal of the Company Relocation Product Development Research Award is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will provide companies or limited partnerships that are willing to relocate all or a substantial portion of their business to Texas with the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award is intended to support companies that will be staffed with a majority of Texas-based employees, including C-level executives.

5. OBJECTIVES

The State of Texas seeks to attract industry partners in the field of cancer care to advance economic development and cancer care efforts in the state. The goal of this award mechanism is to recruit to Texas companies with proven management teams who are focused on exceptional product opportunities to improve cancer care. These companies must presently be domiciled outside of Texas and have sufficient personnel to operate the Texas-based research and/or development activities of the company and, along with appropriate management, must be willing to relocate to or be hired and remain in Texas for a specified period after funding.

The long-term objective of this award is to support commercially oriented therapeutic and medical technology products, diagnostic or treatment-oriented information technology products, diagnostics, tools, services, and infrastructure projects. Common to all applications under this RFA should be the intent to further the research and development of products that would eventually be approved and marketed for the diagnosis, prevention, and/or treatment of cancer. Eligible products or services include—but are not limited to—therapeutics (eg, small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques.

CPRIT seeks to maximize the clinical impact of our funding. Hence, we focus investment in translational research and development activities, including the following eligible stages:

- Studies that establish preclinical proof of concept
- GLP studies to support INDs
- Phase 1 to establish safety and a maximally tolerated dose
- Phase 2 studies to determine safety and efficacy in initial targeted patient populations (up to 100 patients)

CPRIT typically does not fund efforts outside of these parameters. We do not consider studies larger than what are described as "translational" and, hence, such studies are outside the scope of our interest. Companies that have clinically demonstrated safety and efficacy should be able to acquire necessary capital via other sources. By exception, later clinical trials or later-stage product development projects may be considered where exceptional circumstances warrant CPRIT investment.

CPRIT's objectives and program priorities are established by its Oversight Committee. Consistent with the above, these priorities include "funding projects at Texas companies and relocating companies that are most likely to bring important products to the market." A full description of CPRIT's program priorities may be found at http://priorities.cprit.texas.gov/.

6. FUNDING INFORMATION

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development project proposed. Requested funds must be well justified. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property (IP) acquisition and protection, external consultants and service providers, travel in support of the project, and other appropriate research and development costs, subject to certain limitations set forth by Texas law. If a company is working on multiple projects, care should be taken to ensure that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the state. Texas law limits the amount of awarded funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

For companies receiving an initial CPRIT award, CPRIT will contribute \$2.00 for every \$1.00 contributed in matching funds by the company. CPRIT reserves the right to seek a higher matching funds contribution, ie, CPRIT will contribute \$1.00 for every \$1.00 contributed in matching funds by the company, from a company that has already received a CPRIT award and is approved for a second award. The demonstration of available matching funds must be made prior to the distribution of CPRIT funds, not at the time the application is submitted. The matching funds commitment may be fulfilled on a year-by-year basis.

7. KEY DATES

RFA release November 20, 2019

Online application opens December 4, 2019, 7 AM central time

Applications due January 29, 2020, 4 PM central time

Invitations to present sentMarch 2020Notifications sent if not invitedMarch 2020Presentations to CPRIT*April 2020

Award Notification August 2020
Anticipated Start Date September 2020

* Applicants will be notified of their peer review panel assignments prior to the peer review meeting dates. Information on the timing of subsequent steps will be provided to applicants later in the process.

8. ELIGIBILITY

8.1. Applicants

- Either for-profit or non-profit companies may apply. However, non-profit companies
 must intend to bring a product to market. Applications may be submitted prior to
 company formation, but company formation must be completed before award receipt.
 Applicants will be required to provide a data universal numbering system (DUNS)
 number before award receipt.
- Applicants may be located outside the State of Texas when the application is submitted and reviewed. However, CPRIT requires the grant applicant to demonstrate that it will relocate to Texas as a condition of the grant award. A company is considered to be Texas based if it currently fulfills or commits to fulfilling a majority of the following criteria:
 - 1. The US headquarters is physically located in Texas.
 - 2. The Chief Executive Officer resides in Texas.
 - 3. A majority of the company's personnel, including at least 2 other C-level employees (or equivalent) reside in Texas.
 - 4. Manufacturing activities take place in Texas.
 - 5. At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.
 - 6. At least 1 clinical trial site is in Texas.
 - 7. The company collaborates with a medical research organization in Texas, including a public or private institution of higher education.

In exceptional circumstances, the applicant may propose 1 or more alternative location requirements, which the Oversight Committee may approve by a majority vote in an open meeting.

 Unless otherwise specified by the award contract, the company must fulfill all location requirements identified in the application within 1 year of receiving the initial disbursement of funds. Failure to maintain compliance with the location criteria will result in consequences ranging from suspension of grant funding to early termination of the grant contract and repayment of grant funds.

- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools.

 Project must diagnose cancer, treat cancer, or treat sequelae specific to cancer.
- An application last submitted (including resubmissions) before December 22, 2017), may be submitted as a new application, even if it was previously resubmitted.
- CPRIT is releasing 3 Product Development RFAs in this funding cycle. Please note that in any given application round, applicants are allowed to apply for only <u>1</u> Product Development award (TXCO, RELCO, or Seed). Applicants are advised to review each RFA and select the program that best fits their development status.
- Only 1 coapplicant may be included on the application. For the Product Development Research Program, a coapplicant is an individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. If so designated by the applicant organization, coapplicants share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple applicants are named, each is responsible and accountable for the proper conduct of the project, program, or activity, including the submission of all required reports. The presence of more than 1 applicant on an application or award diminishes neither the responsibility nor the accountability of any individual applicant.
- An applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the application, or any company officer or director (or any person related to 1 or more of these individual within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.
- The applicant must report whether the company, company representative, or other
 individuals who contribute to the execution of the proposed project in a substantive,
 measurable way, whether or not those individuals are slated to receive salary or

compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or other individuals are ineligible to receive federal grant funds or have had a grant terminated for cause, the applicant may be contacted to provide more information.

• CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although the applicant need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

8.2. Resubmission Policy

- An application previously submitted to CPRIT within the last 2 years (after December 22, 2017) but not funded may be resubmitted once and must follow all resubmission guidelines. An application that was last submitted before December 22, 2017, may be submitted as a new application, even if the most recent submittal (prior to December 22, 2017), was a resubmission. For additional clarity regarding the 20.2 application cycle, this means that an application that was last submitted during or before the 18.1 cycle is considered a new application. In contrast, an application that was last submitted during or after the 18.2 cycle is considered a resubmission. It is expected that significant progress will have been made on the project; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to submit an application with such modest changes.
- An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the applicant or company representative for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. An application that was administratively withdrawn by the applicant or by CPRIT prior to review by the review panel is not considered a submission for purposes of CPRIT's resubmission policy.

• Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received an overall numerical score of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

9. APPLICATION REVIEW

9.1. Overview

Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. In general, a greater extent of commitment to establishing research and/or development functions in Texas will be viewed more favorably by CPRIT. However, it is left to the applicant's judgment to make a case for what they consider to be a sufficient extent of commitment to Texas.

CPRIT requires the submission of a comprehensive development plan (see <u>section 10.4.7</u>) and a detailed business plan (see <u>section 10.4.8</u>). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and development plans. The plans will be reviewed by an integrated panel of individuals with biotechnology expertise and experience in translational and clinical research as well as in the business development/regulatory approval processes for therapeutics, devices, and diagnostics. In addition, advocate reviewers will participate in the review process.

Funding decisions are made via the review process described below.

9.2. Review Process

- **Product Development and Scientific Review:** Applications that pass initial administrative review are assigned to independent CPRIT Product Development Peer Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of applicants may be invited to deliver in-person presentations to the review panel.
- **Due Diligence Review:** Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional in-depth due diligence, including—but not limited to—IP, management, regulatory, manufacturing, and market assessments. Please note that CPRIT may request to review any correspondence that an applicant has with regulatory agencies (eg, the FDA) as part of the diligence process. Following the due diligence review, applications may be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and IP reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.
- Program Integration Committee Review: Applications recommended by the Product
 Development Review Council will be forwarded to the CPRIT Program Integration
 Committee (PIC) for review. The PIC will consider factors including program priorities
 set by the Oversight Committee, portfolio balance across programs, and available
 funding.
- Oversight Committee Approval: The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, <u>chapter 703</u>, sections 703.6 to 703.8.

9.2.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development Peer Review Panel members, Product Development Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Any form of communication regarding any aspect of a pending application is prohibited between the applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Product Development Review Panel member, or a Product Development Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.3. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application.

The overall assessment will not be an average of the scores of the individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

Attached to this RFA is a list of more detailed questions considered by CPRIT reviewers when assessing therapeutic applications (Appendix 1, "Reviewer Evaluation Guidelines for Therapeutics") and when assessing medical devices, diagnostics, and/or tools (Appendix 2, "Reviewer Evaluations Guidelines for Medical Devices and Diagnostics"). Applicants are encouraged to review these documents and, to the extent possible, address the questions within their application.

9.3.1. Primary Criteria

Primary review criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed program.

The criteria provided below are designed to provide an <u>overview</u> of topics that may be pertinent to the assessment of applications during peer review. Specific criteria applied to evaluate a given application will depend on the type of product described by the applicant (eg therapeutic versus medical device). **Detailed descriptions of the specific criteria employed for different product classes are provided in the appendices to this RFA.**

Primary review criteria are heavily weighted in determining the quality of an application. Reviewers provide numerical scores for these topic areas when evaluating applications. Primary criteria are intended to address the following topics:

- Significance and Impact
- Unmet Medical Need
- Product Validation/Proof of Concept
- Safety
- Preclinical Strength/Development to Date
- Development Plan
- Competitive Landscape
- Intellectual Property
- Business/Commercial Aspects
- Management and Staffing
- Production/Manufacturing Plan
- Overview of Clinical/Regulatory Plan

More details regarding these topics can be found in the appendices to this document.

9.3.2. Secondary Criteria

Secondary review criteria contribute to the global score assigned to the application and are not assigned individual numerical scores. Concerns with these criteria potentially question the feasibility of the proposed research and development activities.

Secondary criteria include the following:

• Budget and Duration of Support

Please see appendices for more details.

10. SUBMISSION GUIDELINES

Applicants are advised to review carefully all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available on December 4, 2019. Applications that are missing 1 or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

10.1. Online Application Receipt System and Application Submission Deadline

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The applicant must create a user account in the system to start and submit an application. The coapplicant, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the applicant) must also create a user account in CARS. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. It is acceptable (and not uncommon) for the applicant to also serve as the designated ASO. However, if the applicant intends to also serve as the ASO, the system requires that the applicant and the ASO have 2 different accounts and user names. Applications will be accepted beginning at 7 AM central time on December 4, 2019, and must be submitted by 4 PM central

time on January 29, 2020. Submission of an application is considered an acceptance of the

terms and conditions of the RFA.

10.2. **Submission Deadline Extension**

The submission deadline may be extended upon a showing of good cause. Late submissions are

permitted only in exceptional instances, usually for technology failures in the CARS. It is

imperative that applicants allow sufficient time to familiarize themselves with the application

format and instructions to avoid unexpected issues. The applicant's failure to adequately plan is

not sufficient grounds to justify approval of a late submission.

Peer review schedules are set far in advance and do not accommodate receipt of an application

days after the deadline. Therefore, potential applicants that are unable to meet the deadline due to

issues such as travel, sabbaticals, conferences, prolonged illness, or other leave, etc, should not

request additional time to submit an application but should instead consider submitting the

application in the next review cycle.

A request to extend the submission deadline must be submitted via email to the CPRIT Helpdesk

within 24 hours of the submission deadline. Submission deadline extensions, including the

reason for the extension, will be documented as part of the grant review process records.

10.3. Product Development Review Fee

All applicants must submit a nonrefundable fee of \$1,000 for review of Product Development

Research applications. Payment should be made by check or money order payable to Cancer

Prevention and Research Institute of Texas; electronic and credit card payments are not

acceptable. The application ID and the name of the submitter must be indicated on the payment.

Unless a request to submit a late fee has been approved by CPRIT, all payments must be

postmarked by the application submission deadline and mailed as described below.

Checks may be mailed via the US Postal Service to the following address:

Cancer Prevention and Research Institute of Texas

PO Box 12097

Austin, Texas 78711

Contact name: Michelle Huddleston

Phone 1-512-305-8420

CPRIT RFA C-20.2-RELCO (Rev 11/20/19)

Company Relocation Product Development Research Awards

p.18/41

Mail sent via a delivery services (ie, FedEx, UPS, etc) will need to use this address:

Cancer Prevention and Research Institute of Texas

Wm B Travis State Office Building

1701 N Congress Ave Ste 6-127

Austin, Texas 78701

Contact name: Michelle Huddleston

Phone 1-512-305-8420

10.4. **Application Components**

Applicants are advised to minimize repetition among application components to the extent possible. In addition, applicants should use discretion in cross-referencing sections in order to maximize the amount of information presented within the page limits.

Please note that letters of commitment and/or memoranda of understanding from community organizations, key faculty, etc, are **not** required or requested. Please do not submit letters of support as part of your application package. Any such information will be removed from your application before review.

10.4.1. Layperson's Summary (1,500-character maximum)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see section 2). Would it fill a needed gap in patient care or in the development of a sustainable oncology industry in Texas? Would it synergize with Texas-based resources? Describe the overall goals of the work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Clearly address how the company's work, if successful, will have a major impact on the care of patients with cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. The layperson's summary will also be used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

10.4.2. Abstract and Significance (5,000-character maximum)

Coherently explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Address how the proposed project, if successful, will have a major impact on the care of patients with cancer. Describe how this application provides a path for acquiring proof-of-principle data necessary for next-stage commercial development. Clearly explain the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

10.4.3. Goals and Objectives (maximum of 1,200 characters each)

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success if the award is made. Identify time-specific references as follows: Year 1, Quarter 1 (Y1Q1), Y1Q2, etc. Do not specify actual calendar dates as this can be confusing when dates change.

10.4.4. Timeline (1-page maximum)

Provide a visual depiction of anticipated major milestones to be tracked in the form of a Gantt chart. Identify time-specific references as follows: Y1Q1, Y1Q2, etc, as opposed to naming specific months and years. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

10.4.5. Slide Presentation (10-page maximum)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with 1 slide filling each landscape-orientated page. The slides should succinctly capture all essential elements of the application and should stand alone.

10.4.6. Resubmission Summary (1-page maximum)

If this is a resubmission, upload a summary of the approach, including a summary of the applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

Note: An application submitted or resubmitted before December 22, 2017, may be submitted as a new application, even if it was previously resubmitted. For the "new" applications, no summary is required.

10.4.7. Development Plan (12-page maximum)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. Describe the label claims that the company ultimately hopes to make, and describe the plan to gather evidence to support these claims. Outline the steps to be taken during the proposed period of the award, including the design of the translational and/or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches to these risks. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The development plan should include a defined **target product profile (TPP)** or analogous document for a medical device, in vitro diagnostic, or service that projects a clear path to full commercialization (see

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm 080593.pdf). The TPP provides a statement of the *overall intent* of the product development program and gives information about the product *at a particular time* in development. Usually, the TPP is organized according to the key sections in the product package insert for a drug or biologic or medical device labeling and links development activities to specific concepts intended for inclusion in the product labeling. CPRIT recognizes that many applications are early in the development process and that not all elements of the TPP will be known at the time of

application. Consequently, not only does the TPP serve as a snapshot in time of the development status of the program, but it additionally serves as an aspirational target upon eventual commercialization. The TPP should include the parameters below; the questions are intended to guide the thinking process and may include, but are not limited to, the examples provided.

- Identification of a target that is applicable to human cancer treatment. Is intervention with this target likely to lead to a therapeutic, medical device, diagnostic, or service that could be useful in the treatment of cancer?
- Selection of a lead compound, assay, or device technology based on the target. Is the identification of potential developmental candidates based on a set of in vitro tests followed by selection of a lead candidate based on considerations (as appropriate for the candidate) of pharmacodynamic parameters and the results of preclinical, in vivo, proof-of-principle studies in relevant animal models of disease?
- Description of a high-level clinical development plan detailing each of the clinical studies supporting marketing approval (phase 1, 2, and 3) the preclinical work is meant to support. Designing the preclinical program requires an understanding of the duration of the clinical studies required by regulatory authorities. Consequently, a brief outline of each of the phase 1, phase 2, and phase 3 studies necessary to obtain regulatory approval and reimbursement funding must be sketched out prior to deciding which toxicology studies would be required.

Applicants developing cancer therapeutics are encouraged to become familiar with FDA guidance documents for submission of applications related to new product development. These documents provide a standard framework for new drug submissions and biologic license applications to the FDA. Utilizing this framework helps ensure that the submission to CPRIT contains all relevant elements and is optimally organized.

Additionally, for therapeutics, the following apply:

Intended route of administration and dosing regimen. Is the intended route of administration and dosing regimen consistent with accepted convention and medical need for the therapeutic, or will the use of this new agent require a paradigm shift (more frequent or less frequent dosing, new route or method of administration), and if so, what impact will it have on current standard of care?

Optimization of the lead to ensure desired characteristics, including, but not limited to, the following studies:

- Indication of the threshold of both the safety and efficacy necessary to be a competitive product when the product is introduced
- Absorption, distribution, metabolism, excretion, including, but not limited to, relevant studies based on route of administration
- Safety (studies as mandated by ICH guidelines)
- Biomarkers (assays) that potentially target specific patient populations for clinical trials
- Biomarkers (assays) that can serve as potential pharmacodynamic markers of clinical activity during early clinical trials designed to demonstrate proof of concept
- Proposed current good manufacturing practice (including estimated costs) that can be scalable from phase 1 through phase 2. Include information on whether there are plans for possible formulation.

The FDA's website provides "Common Technical Documents" (CTDs, see https://www.ich.org/page/ctd) for guidance documents. There are 3 CTDs covering safety, efficacy, and quality. This guidance presents a standard format for the preparation of a well-structured application. Applicants may condense or summarize the CTD format as they deem appropriate to meet page limitations.

While originally intended for regulatory authorities, these formats are also applicable for a CPRIT application. Many of our reviewers have extensive pharmaceutical development expertise and are familiar with these standard formats. Hence, utilizing the CTD format will simplify the review and ensure that the application contains all of the relevant elements.

CPRIT recognizes that many applications are early in the product development process. Hence, not all elements of the CTD will be known at time of CPRIT application. We encourage applicants to complete as much of the Safety and Efficacy CTD sections as possible and to follow the submission format prescribed.

References for the Development Plan section should be provided as a stand-alone document that will be separately uploaded into CARS. In the interests of brevity include only the most pertinent and current literature. While references will not count toward the Development Plan section page limit, it is essential to be concise and to select only those references relevant to the development

plan. Do not use the references to circumvent Development Plan section page limits by including data analysis or other nonbibliographic material.

The development plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by a highly qualified panel of reviewers. To the extent possible, the development plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred. Please avoid redundancy!

10.4.8. Business Plan

CPRIT can only provide a portion of the funds required to successfully develop a novel product or service. Companies typically need to raise substantial funds from private sources to fully fund development. Hence, we require companies to provide a business plan that summarizes the rationale for investing in this project. Private investors will seek a financial return on their investment. They will need to be convinced that this project has high investment return potential based on its risk profile. They typically focus on market opportunity size, development path, and key risk issues.

Successful applicants will provide a thoughtful, careful, and succinct rationale explaining why this program is an appropriate investment of CPRIT and private funds. Note that if the company is selected to undergo due diligence, additional information to support the application will be requested at that time. Award applicants will be evaluated based not only on the current status of the components of the business plan but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

Please provide an overview of the business rationale for investing in this project. The business rationale overview will be 2 pages maximum. In addition, please provide summaries of the following key development issues with a maximum of 1 page each.

1. **Product and Market:** Provide an overview of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care, ie, primary therapy, second-line therapy, adjunctive to current therapies, etc. Information on patient populations and market segments is helpful.

- 2. **Competition and Value Proposition:** Provide an overview of the competitive environment (current and future) and how the envisioned product will compete in the marketplace. Provide information on how the clinical utility (efficacy, safety, cost, etc) of this therapy compares with current and potential future therapies. A clear delineation of competitive advantages and data demonstrating these advantages are helpful.
- 3. Clinical and Regulatory Plans: Provide a detailed regulatory plan, including preclinical and clinical activities and the regulatory pathway for major markets. Please describe how this is driven by interactions with the FDA, if possible. The regulatory plan should include regulatory communications (including all interactions to date with the FDA) and strategy, with clarity provided on regulatory matters and current regulatory strategies.
- 4. **Pricing and Reimbursement:** Provide an overview of the product cost and anticipated revenue. Cost, price, and reimbursement references from similar products are helpful. An overview of how the company plans to obtain CMS and private insurance reimbursement approval is also helpful.
- 5. **Commercial Strategy:** Provide an overview of your financial projections and how you will generate a return on this investment. Describe how the company plans to bring the product to market. Information on physicians to be targeted, sales channels, etc, is helpful. Alternatively, many drugs are acquired by large pharma firms in the late development stages. If the company plans to seek acquisition, please provide an overview of similar transactions. Provide a brief assessment of current competition.
- 6. **Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated. Key risk issues typically include efficacy versus competitors, toxicity, clinical trials, FDA approval, dosage and delivery, CMC synthesis, changing competitive environment, etc.
- 7. **Funding to Date:** Provide an overview of the funding received, including a list of funding sources and a comprehensive capitalization table that should comprise all parties who have investments, stock, or rights in the company. A template exemplifying an appropriate capitalization table is provided among the application materials. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.

- 8. **Intellectual Property:** Provide a concise discussion of the IP issues related to the project. List any relevant issued patents and patent applications. Please include the titles and dates the patents were issued/filed/published. List any licensing agreements that the company has signed that are relevant to this application.
- 9. Key Personnel Located in Texas and Any Key Management Located Outside of **Texas:** For each member of the senior management and scientific team, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, current geographic location (in particular, whether they are located within Texas) and any other information considered essential for evaluation of qualifications. Key personnel are the Principal Investigator/Project Director as well as other individuals who contribute to the development or the execution of the project in a substantive, measurable way. Substantive means they have a critical role in the overall success of the project and that their absence from the project would have a significant impact on executing the approved scope of the project. *Measurable* means that they devote a specified percentage of time to the project. The indicated time is an obligatory commitment, regardless of whether or not they request salaries or compensation. "Zero percent" effort or "TBD" or "as needed" are not acceptable levels of involvement for those designated as key personnel. While all participants that meet these criteria should be identified as "key," it is expected that the number of key personnel will be kept to a minimum.

The entire Business Plan section shall typically comprise a maximum of 11 pages: a 2-page overview and nine, 1-page key issue summaries. <u>Please avoid redundancy</u>. Note that the section "Funding to Date" above may exceed this 1-page limit <u>if necessary</u>.

10.4.9. Biographical Sketches of Key Scientific Personnel (8-page maximum)

Provide a biographical sketch for up to 4 key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages. You may use the "Product Development Research Programs: Biographical Sketch" template but are not required to do so. The NIH biographical sketch format is also appropriate. (In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan [see section 10.4.8]).

10.4.10. Relocation Commitment to Texas (1-page maximum)

Provide a timetable with key dates indicating the applicant's plan and commitment to relocate the company to Texas. In addition, describe which personnel and management will be headquartered in Texas.

10.4.11. **Budget**

In preparing the requested budget, applicants should be aware of the following:

- Each award mechanism allows for up to a 3-year funding program with an opportunity for extension after the term expires. **The budget must be aligned with the proposed milestones.** Financial support will be awarded based upon the breadth and nature of the project proposed. Requested funds must be well justified. Funding will be tranched and milestone driven.
- CPRIT considers equipment to be items having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit. If awarded, management of your grant will be facilitated if specific equipment is clearly identified in the application using plain language. Equipment not listed in the applicant's budget must be specifically approved by CPRIT subsequent to the award contract.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.
- The total amount of CPRIT funds allowed for an annual salary of an individual for FY 2020 is \$200,000. In other words, an individual may request salary proportional to the percent effort up to a maximum of \$200,000. Salary amounts in excess of this limit must be paid from matching funds. Salary does not include fringe benefits. CPRIT FY 2020 is from September 1, 2019, through August 31, 2020. Additionally, adjustments of up to a 3% increase in annual salary are permitted for Years 2 and 3 up to the cap of \$200,000. The salary cap may be revised at CPRIT's discretion.

The Budget section is composed of 4 subtabs that must be completed:

A. Budget for All Project Personnel: Provide the name, role, appointment type, percent effort, salary requested, and fringe benefits for all personnel participating on this project.

- If funding is requested for a role that is not currently occupied, applicant should note "new hire" as name.
- **B.** Detailed Budget for Year 1: This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs in the first year of the project. Direct cost categories include Travel, Equipment, Supplies, Contractual (Subaward/Services Contracts), or Other. Applicants will be required to itemize costs.
- C. Budget for Entire Proposed Period of Performance: This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs for all subsequent years. Amounts for *Budget Year 1* will be automatically populated based on the information provided on the previous subtabs; namely, *Budget for All Project Personnel* and *Detailed Budget for Year 1*.
- D. Budget Justification: Please specify your CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds. Please specify each line item from your CPRIT budget as well as other funds (including matching funds). Provide a compelling justification for the budget for each line item of the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. If travel costs will include out-of-state or international travel, make that clear here. The budget must be aligned with the proposed milestones.

11. AWARD ADMINISTRATION

Texas law requires that CPRIT awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to entities, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and IP rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10 to 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

Project Revenue Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement, which can be found at www.cprit.texas.gov and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has appropriate matching funds. For companies receiving an initial CPRIT award, the company must contribute \$1.00 in matching funds for every \$2.00 awarded by CPRIT. CPRIT reserves the right to seek a higher matching funds contribution, ie, the company will contribute \$1.00 in matching funds for every \$1.00 awarded by CPRIT, from a company that has already received a CPRIT award and is approved for a second award. Matching funds need

not be in hand when the application is submitted, nor does the entire amount of matching funds for the full 3 years of the project need to be available at the start of the grant. However, the appropriate amount of matching funds for each specific tranche must be obtained before each tranche of CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be targeted for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements associated with the requirement to demonstrate available funds.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific and product development aspects of applications. Before contacting the helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS. In addition, for Frequently Asked Programmatic Questions, please go here and for Frequently Asked Technical Questions, please go here.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time

Tel: 866-941-7146 (toll free in the United States only—international applicants

should use the email address below)

Email: Help@CPRITGrants.org

13.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Product Development Research Program Senior Manager.

Tel: 512-305-7676

Email: Help@CPRITGrants.org

Website: www.cprit.texas.gov

14. APPENDIX

14.1 Reviewer Evaluation Guidelines for Therapeutics

Primary Review Criteria (Scored)

Unmet medical need: Target Product Profile (TPP)

- Assuming successful accomplishment of development objectives, as reflected in the target product profile, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
- In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

Target Validation

- If this is a "targeted" agent, to what extent has the target been validated, eg, through knockdown studies and/or pharmacological intervention?
- Has engagement of the target with the agent been demonstrated by biochemical assay?
 What is the potency of the agent?
- Are there validated downstream pharmacodynamic (PD) markers of target modulation? How extensive is the in vitro evidence for expected PD effects? Has the agent shown biologically significant modulation of the target in vivo, especially in tumor tissue?
- Is the target uniquely or substantially overexpressed by tumor versus normal cells?
- Does the target represent an activating mutation? If so, has binding of the agent to the target and other activating mutations been characterized?
- Has the company's demonstration of target validation been externally/independently confirmed?
- Are there known mechanisms of resistance to the modulation of this target? If so, has the company proposed possible mitigation/preemptive approaches, such as combination chemotherapy?

Preclinical Characterization: Pharmacodynamic Proof of Concept

- Considering in vivo preclinical pharmacodynamic characterization and the patient populations or subpopulation(s) representing the initial clinical indication(s) for the drug, what is the clinical relevance of the preclinical models? To elaborate, were in vivo/xenograft studies carried out in cell line-based models or PDX-derived models? In how many such models have studies been carried out? To what extent do these models reflect standard of care (SOC) for refractory versus drug-naive tumors? At the time of treatment initiation, were tumors established and measurable, or was treatment initiated shortly after tumor inoculation?
- Was antitumor activity predominantly growth inhibition or tumor regression? Were sustained complete remissions or "cures" achieved in the majority of animals and models? Were comparisons with optimally dosed SOC agents made? Where the agent is intended to be added to the SOC, is there compelling evidence of in vitro/in vivo synergy with SOC agents?
- Have results of preclinical pharmacodynamic studies carried out by the company been externally/independently confirmed?
- Overall, considering clinical relevance and study results, how strong is the preclinical efficacy profile of the agent?
- How strongly does the preclinical pharmacodynamic profile support the clinical efficacy expectations reflected in the TPP?

Preclinical Characterization: Safety

- How extensive is the in vitro and in vivo preclinical safety characterization carried out so far?
- Has the agent undergone CEREP-type screening for interactions with targets with known safety liabilities, eg, CYP 450, hERG?
- Considering potency and target selectivity, what is the potential both for off-target and pharmacologically on-target deleterious effects?
- Can exposures associated with substantial antitumor efficacy/PD effects be achieved safely in vivo?

- Do preclinical pharmacokinetics (PK) studies indicate potential for clinical safety issues, eg, accumulation, variability, lack of dose proportionality?
- Have PK/PD issues been investigated with alternate dosing schedules in order to optimize the therapeutic index of the agent?
- Are there any issues with the distribution or metabolism of the agent?
- Overall, are results of safety characterization carried out so far such that the agent can be considered reasonably derisked from a safety perspective, or are there red flags?
 Alternatively, is the extent of preclinical safety characterization carried out so far insufficient to address this question?

Pharmaceutical Properties/Chemistry and Pharmacy

- In the case of agents intended for oral absorption, are there any issues with water solubility? Do formulation studies indicate the feasibility of oral administration?
- Were Lipinski-type criteria applied during the lead optimization process such that the lead compound has demonstrated properties that make it likely to be an orally active drug in humans?
- Are there any issues with the stability of the drug substance or the drug product?
- Is there scope for further lead optimization through structure activity studies?
- In the case of biologicals, has a high-quality cell line been developed yet? Are yields acceptable? Does the purification process appear reasonable and scalable?
- Have analytical methods been adequately developed?
- Has the (lead) protein been adequately characterized biochemically, immunogenetically, and biophysically? Has absence of aggregate formation been demonstrated in stability studies?

Development Plan/Regulatory Aspects

- Are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date?
- Does the applicant demonstrate adequate familiarity with pertaining regulatory guidelines in major jurisdictions (United States/European Union)? Do development proposals reflect specific regulatory authority input, eg, from pre-IND interactions? Alternatively, has regulatory authority interaction been insufficient so far?

- In the case of clinical studies, are patient populations adequately described and consistent with those representing the initial target indication(s)?
- Are efficacy end points appropriate for study designs? Is the sample size statistically adequately justified in terms of the target effect size?
- In the case of potentially pivotal clinical trials, moreover, are the proposed primary efficacy end points and target effect sizes consistent with regulatory precedence?
- Considering target indication prevalence, will the agent qualify for orphan drug designation? If so, does the applicant intend to apply for this?
- Has the applicant demonstrated reasonable diligence in researching patient availability, competitive clinical trial activity, and recruitment issues such that patient enrollment projections can be considered realistic?
- Will the proposed programs advance development of the agent to commercially significant milestone(s), such as might attract either partner interest or the raising of further development funding?
- Are development milestones clear and adequately described? Is the overall project timeline realistic?

Competitive Analysis

- Has the applicant carried out a comprehensive and realistic analysis of the likely strengths and weaknesses of the agent compared to clinically relevant competitive products, including potentially competitive agents in development?
- Are the applicant's assumptions regarding the strengths and weaknesses of the agent relative to likely competitors reasonable, considering the preclinical efficacy and safety data on the agent generated so far?

Intellectual Property/Freedom to Operate

- Have IP and freedom-to-operate aspects been addressed in the application?
- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate?

Chemistry, Manufacturing, and Controls (CMC)

- How advanced is CMC and manufacturing development?
- Are there any sourcing issues?
- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- Are there significant technical difficulties within CMC/manufacturing scale up still to be addressed?

Business/Commercial Aspects

- Does the applicant need to raise further funds for the CPRIT matching requirement? In this case, how realistic are the applicant's assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program of studies reasonably support such expectations?
- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?

Management Team

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as translational research, clinical development, regulatory affairs, and CMC/manufacturing? If not, are there plans to address such deficiencies?
- Has the applicant demonstrated appropriate engagement of outside development expertise through, for example, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Is it clear that no CPRIT funds will be sent out of Texas to a corporate headquarters?

14.2 Reviewer Evaluation Guidelines for Medical Devices and Diagnostics

Primary Review Criteria (Scored)

Unmet Medical Need

- Assuming successful accomplishment of development objectives, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
- In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

Product Validation

- Technical Validation: Has the product or technology been successfully validated, ie, prototyped, built and tested in ex vivo, animal, or clinical settings?
- Have biological proof of principle and product mechanism of action been demonstrated?
- Have efficacy and safety in an accepted in vitro or animal model been demonstrated?
- Clinical Validation: Are clinical trials required to demonstrate product performance? If so, have they been planned or conducted?
- Biological Risk: What are the risks to the patients, eg, toxicology, biological, interactions with other therapies?

Production/Manufacturing

- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- How advanced is manufacturing development?
- Are there any sourcing issues?

Intellectual Property/Freedom to Operate

- Have barriers to entry been identified? Has a route to patentability been mapped out, eg, independent patent, first-mover advantage, unique know-how, etc?
- Does the company have issued patents? If not, have they conducted freedom-to-operate and patentability analysis?
- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use), and duration of patent life, how strong is the IP?

- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate, if required?

Market Opportunity

- Does the product address a clearly defined unmet need; lack of available therapy, poor efficacy, side effects, lack of available diagnostic, safety problems, cost reduction, enhanced convenience?
- Are target indication and market clearly defined?
- Is channel to market available? Does the company understand the entire value chain and all constituencies involved in procuring and utilizing the product?
- Does the company understand the clinical pathway that leads to utilizing the product?
- Is market opportunity of significant size and lucrative enough to justify investment?
- Has the applicant demonstrated time or cost savings?
- How does product fit with the existing "ecosystem"; ie, are the benefits provided worth the time and cost of implementing the new approach?

Competition

- Is this a "Whole Product," ie, a complete product or service sold to a defined customer that provides a defined value proposition?
- Is value proposition clearly delineated, ie, improve efficacy, improve safety, reduce cost, or improve convenience?
- Has the company demonstrated its value proposition versus competition?
- Has the company conducted a competitive analysis? Does it provide a comprehensive, realistic assessment of strengths and weakness versus competition based on the data generated to date?

Development Plan/Regulatory Aspects

- Have a comprehensive development plan and market entry strategy been developed?
 How realistic are these plans?
- Has determination of FDA-defined device classification been completed? Is the clinical and regulatory pathway well understood and feasible?

Management Team

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as product engineering, clinical development, regulatory affairs, manufacturing, etc? If not, are there plans to address such deficiencies?
- Has the applicant demonstrated appropriate engagement of outside development expertise through, eg, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Business/Commercial Aspects

- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration, and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?
- Has the company clearly anticipated pricing strategy and reimbursement environment?
- Is the projected return on investment congruent with investment opportunity and risks?

Funding

- Is investor interest in this sector sufficient to fund the company through profitability?
- Does the applicant already have available funds to meet the CPRIT matching requirement, or do they need to raise additional funds? In this case, how realistic are assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
- Have likely acquirers been identified by the applicant?
- Does the company have the resources to support required activities while fundraising?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program reasonably support such expectations?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Does the applicant demonstrate an understanding of the Texas spending requirement for CPRIT funds?

Third Party Observer Reports



Cancer Prevention and Research Institute of Texas (CPRIT) 20.1 Product Development Research Product Development Panel - 2 Meeting (PDR_PDP_20.1) Observation Report

Report No. 2019-09-25 PDR_PDP-2_20.1 Program Name: Product Development Research

Panel Name: 20.1 Product Development Research Product Development Panel -

1 Meeting (PDR_PDP-2_20.1)

Panel Date: 09-25-2019 Report Date: 09-30-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 20.1 Product Development Research Product Development Panel - 2 Meeting (PDR_PDP-2_20.1). The meeting was chaired by Jack Geltosky and conducted via teleconference on September 25, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information:
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

 The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Fourteen (14) applications were discussed and six
 (6) were not discussed
- Panelists: One (1) panel chair, twelve (12) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were twelve (12) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA

Senior Partner

Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney



Cancer Prevention and Research Institute of Texas (CPRIT) 20.1 Product Development Research Product Development Panel - 2 (20.1 PDR PDP-2) Observation Report

Report No. 2019-10-25 20.1_PDR_PDP - 2 Program Name: Product Development Research

Panel Name: 20.1 Product Development Research Product Development Panel -

2 (20.1 PDR PDP-2)

Panel Date: 10-24 and 10-25-2019

Report Date: 11-13-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 20.1 Product Development Research Product Development Panel - 2 (20.1_PDR_PDP-2) meeting. The meeting was chaired by Jack Geltosky and conducted in-person on October 24 and October 25, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Eight (8) applications were discussed
- Panelists: One (1) panel chair, eleven (11) expert reviewers and two (2) advocate reviewers on day 1 and one (1) panel chair, ten (10) expert reviewers and two (2) advocate reviewers on day 2
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5) and two (2) additional GDIT or contract staff
 participated intermittently in a technical or logistics support role on day 1 and
 Five (5) and three (3) additional GDIT or contract staff participated intermittently
 in a technical or logistics support role on day 2
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eight (8) COIs identified prior to and/or during the meeting. An appearance of a COI was discovered after the discussion of application DP200005. A husband and wife, who are both Venture Partners in the same firm were on the PDP Panel 2 as expert reviewers. Both parties were excluded from the teleconference which brought the application forward. However, only the husband was excluded from the in-person meeting as the wife was deemed not to have a conflict. The husband panelist with a COI who exited for DP200005 returned prior to the conclusion of the meeting. The meeting was immediately stopped, and the panelist asked to leave. Upon exit of the panelist the meeting continued. As panelists exited for break the COI panelist entered and began a discussion with his wife which appeared to concern application DP200005 as both proceeded to the exit. The third-party observer immediately notified CPRIT Program Staff of the incident. The COI panelist and his wife's discussion was deemed by CPRIT to concern a personal matter. Both parties were asked to exit as COIs for the remaining COIs for which one or the other had a conflict. Remaining COIs were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA

Senior Partner

Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney



Cancer Prevention and Research Institute of Texas (CPRIT) 20.1 Product Development Review-Due Diligence Panel (PDR_DD_20.1) Observation Report

Report No. 2020-01-13 PDR DD 20.1

Program Name: Product Development Research

Panel Name: 20.1 Product Development Due Diligence Panel (PDR_DD_20.1)

Panel Date: 01-13-2020 Report Date: 01-15-2020

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 20.1 Product Development Due Diligence Panel (PDR_DD_20.1). The meeting was chaired by Jack Geltosky and was conducted via teleconference on January 13, 2020.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

_

 The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed
- Panelists: Fourteen (14) expert reviewers
- ICON employees: Five (5)
- IP Attorneys: Two (2)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA

Senior Partner

Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney



<u>Cancer Prevention and Research Institute of Texas (CPRIT)</u> <u>20.1 Product Development Research - Due Diligence Panel-2</u> (<u>20.1 PDR DDP-2</u>) <u>Observation Report</u>

Report No. 2020-03-17 20.1_PDR_DDP-2
Program Name: Product Development Research

Panel Name: 20.1 Product Development Research Due Diligence Panel-2

(20.1_PDR_DDP-2)

Panel Date: 03-17-2020 Report Date: 03-31-2020

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 20.1 Product Development Research Due Diligence Panel-2 (20.1_PDR_DDP-2). The meeting was chaired by Jack Geltosky and was conducted via teleconference on March 17, 2020.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

20.1 Product Development Research Due Diligence Panel-2 Meeting (20.1_PDR_DDP-2) Page 2

• The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed
- Panelists: One (1) panel chair and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

20.1 Product Development Research Due Diligence Panel-2 Meeting (20.1_PDR_DDP-2) Page 3

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA

Senior Partner

Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer

Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Product Development Research Cycle 20.1 Applications
Product Development Research Cycle 20.1 Applications Announced at the February 19, and May 20, 2020, Oversight Committee Meetings

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Research Cycle 20.1 include Seed Awards for Product Development Research, Company Relocation Product Development Awards; and Texas Company Product Development Awards. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Organization/Company	Conflict Noted					
Applications considered by the PIC and Oversight Committee								
DP200056	Neil Thapar	Barricade Therapeutics, Corp.	Diane Amy Trainor;George. Trainor;Leila Alland					
Applications not considered by the PIC or Oversight Committee								
DP200023	Sohail Syed	Theracle, Inc.	Bo Saxberg					
DP200059	Cohava Gelber	Stromatis Pharma, LLC	Bo Saxberg;Marcia Moore;Neil Spector					
DP200005	Upendra Marathi	7 Hills Pharma LLC	George Trainor; Leila. Alland					
DP200016	Alex Stojanovic	Oncolyze, Inc.	Yueming Li					
DP200021	Stephan Morris	Ohm Oncology Inc.	Yueming Li					
DP200026	Judith Leopold	Mekanistic Therapeutics	Judith Fox;Leila Alland					
DP200037	Leah DiMascio	DGD Pharmaceuticals, Corp.	Diane Amy Trainor; George. Trainor; Leila Alland					
DP200049	Eric Zhang	AKSO Biopharmaceutical, Inc.	Leila Alland					

T.A.C. Section 702.19 Waiver



MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

SUBJECT: T.A.C. § 702.19 WAIVER FOR THE CPRIT PRODUCT DEVELOPMENT

REVIEW COUNCIL

DATE: NOVEMBER 18, 2019

This is to notify the Oversight Committee that I have granted a waiver from the general prohibition against communicating directly with grant applicants to the members of the Product Development Review Council (PDRC) pursuant to the authority provided in T.A.C. § 702.19(e). The waiver is effective for the following individuals in review cycle 20.1: Jack Geltosky, David Shoemaker, Colin Turnbull, Roy Cosan, Neil Spector, Kelly Bolton, and Bo Saxberg, and limited to communications with applicants currently undergoing due diligence as described in this notice. No Oversight Committee action related to this waiver is necessary.

CPRIT administrative rule § 702.19 prohibits substantive communication between a grant applicant and a member of the review panel, the Program Integration Committee (PIC), or the Oversight Committee while the application is pending a final decision. CPRIT intends the communication restriction to prevent even the appearance of unequal treatment during the grant review process. However, CPRIT's administrative rule recognizes that there may be a scenario where the need for a reviewer to communicate directly with an applicant during the review process outweighs the reasoning behind the general prohibition. In that case, CPRIT's rule authorizes the Chief Executive Officer to grant a waiver and notify the Oversight Committee of the waiver and its justification.

In this case, the communication waiver is necessary because CPRIT has made modifications to improve the process for the business due diligence conducted by ICON, CPRIT's third-party vendor, for review cycle 20.1 product development applications. ICON develops its final business due diligence report on each company after gathering information from company representatives about various issues raised by the review panels during peer review. PDRC members evaluate the final ICON reports when making award recommendations. To improve the information-gathering portion of the due diligence process for review cycle 20.1, CPRIT has modified the process to assign at least one PDRC member to participate in the informational call between ICON and the applicant so that the reviewer can seek additional clarification, if necessary, on behalf of the review panel regarding points raised during the initial appraisal of the application.

Granting the waiver does not result in unfair or unequal treatment for any application. Although the assigned PDRC member may communicate directly with an applicant during the ICON call to ask follow-up questions or refine additional points, every application undergoing due diligence review will be subject to the same process. CPRIT will make ICON's final due diligence report available to the full PDRC and CPRIT will include documentation of the waiver in the publicly available grant records for product development research awards in review cycle 20.1.

High Level Summary of Due Diligence

RELOC

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following RELOC Company Product Development Research grant award:

• Invectys USA, Inc. for \$14,196,990. The PDRC has recommended no contract contingencies for this award.

Invectys USA, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Invectys USA Inc. is developing a novel human leukocyte antigen G (HLA-G) CAR-T platform for the treatment of solid tumors that have been shown to be resistant to immunotherapy. The Invectys approach is to reprogram immune cells to become killer cells for any tumor cells that express HLA-G. This would potentially increase responsiveness to immunotherapy in many cancer patients. If this application is recommended for funding, the company would relocate to Texas from Paris, France.

Invectys USA Inc. has proposed to use CPRIT funding to conduct early clinical studies to advance its novel CAR-T platform. The proposed Invectys project is focused on the HLA-G molecule, a powerful modulator of the human immune system. HLA-G protects the fetus from the mother's immune system. However, in cancer tumors, cells are selected that express HLA-G to protect the tumor from attacks of the immune system. There are very few cell surface molecules that are so specific, and by comparison, current targets in immunotherapy are far less specific.

Cellular immunotherapy is a powerful new weapon in the anti-cancer arsenal, and the research community has made rapid progress in this area. However, only a small percentage of patients respond. The Invectys approach is to reprograms immune cells to become killer cells for any tumor cells that express HLA-G. This would potentially increase responsiveness to immunotherapy in many cancer patients.

Select reviewer comments summarize the significance and impact as follows:

- Target well-validated by prestigious laboratory as the basis for founding the company, and biology established across multiple laboratories.
- The development proposal appears scientifically sound and next steps are appropriate given the still relative early stage of the project.

- The Board and current investors have agreed to provide a 1:1 match to any CPRIT funding which puts this proposal in a very favorable position from the perspective of funding. In addition, since its inception in 2010, the company has successfully raised >\$40M which establishes a certain track record of success.
- Development of this CAR-T cell treatment targeting HLA-G on cancer cells and in the microenvironment around these cells could be very profitable. It is possible that this could be used for not only solid tumors but also heme cancers, which would be a broad application.
- This is a well written application seeking funding to pursue a high value & high interest cellular therapeutic approach against a novel target in that space which would significantly advance the field of cellular therapy.

De-Identified Overall Evaluation Scores

Company Relocation Product Development Research Awards

Product Development Research Cycle 20.1

In this mechanism, one application is recommended ahead of another application with a better score. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio.

Application ID	Final Overall Evaluation Score
DP200034*	3.3
Α	3.2
В	3.5
С	3.8
D	4.3
E	4.5
F	4.5
G	4.6
Н	4.8
1	5.2
J	5.3
К	5.8
L	6.3
М	6.8
N	6.8
0	6.8

^{*=}Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

April 20, 2020

Donald "Dee" Margo
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to dee@deemargo.com
Via email to Dee Margo's assistant, Olivia Zepeda: ozepeda@deemargo.com

Wayne R. Roberts
Program Integration Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Dee and Wayne,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for one (1) application from CPRIT's Product Development Research 20.1 grant award cycle. The PDRC convened on March 17, 2020 and recommends that the Program Integration Committee and the Oversight Committee approve a Product Development Research grant award for the following applicants: Invectys USA Inc.

The one (1) application for recommendation by the PDRC is an application for which the PDRC had taken "No Action" at its January 13, 2020 Diligence Meeting (Product Development Cycle 20.1), pending review of additional information requested from the applicant. The applicant provided additional information as requested, which was reviewed by the PDRC at the March 17, 2020, Diligence Meeting. As a result of the March 17, 2020, Diligence Meeting, the PDRC recommended to approve an award for applicant Invectys USA Inc.

The PDRC did not make any changes to the proposed goals and objectives, timeline or budget for the one applicant recommended for funding.

The application included in the PDRC's recommendation reflects 50+ hours of individual review and panel discussion of the applicant's proposal as well as the PDRC's review of the due diligence report. Our recommendation is consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

Sincerely,

Jack Geltosky, PhD

Hal tousky

Chair, CPRIT Product Development Review Council

Attachment

Product Development Review Council Award Recommendations

FY 2020 Cycle 1

Rank	Application ID	Mechanism (Cycle)	Company Name	Project	Maximum Recommended Budget	Overall Score*
1	DP200034	RELCO (20.1)	Invectys USA Inc.	CARGo: a CAR-T cell program targeting HLA-G - a novel immune checkpoint and tumor specific antigen for advanced clear cell renal and ovarian carcinomas	\$14,196,990	3.3
				Total	\$14,196,990	

^{*} average reviewer score from in-person peer review



CEO Affidavit Supporting Information

FY 2020 Cycles 20.7 through 20.9 Recruitment of Established Investigators

Request for Applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-20.1-REI

Recruitment of Established Investigators

Please also refer to the Instructions for Applicants document, which will be posted on June 21, 2019

Application Receipt Dates:

June 21, 2019-June 20, 2020

FY 2020

Fiscal Year Award Period September 1, 2019-August 31, 2020

TABLE OF CONTENTS

1. ABOUT CPRIT	4
1.1. ACADEMIC RESEARCH PROGRAM PRIORITIES	4
2. RATIONALE	5
3. RECRUITMENT OBJECTIVES	5
4. INSTITUTIONAL COMMITMENT	6
5. FUNDING INFORMATION	7
6. ELIGIBILITY	
7. RESUBMISSION POLICY	
8. RESPONDING TO THIS RFA	
8.1. APPLICATION SUBMISSION GUIDELINES	
8.2. APPLICATION COMPONENTS	
8.2.1. Summary of Nomination (2,500 characters)	
8.2.2. Institutional Commitment (3 pages)	
8.2.3. Letter of Support from Department Chair (1 page)	
8.2.4. Curriculum Vitae (CV)	
8.2.5. Summary of Goals and Objectives (2,000 characters)	13
8.2.6. Research (4 pages)	
8.2.7. Research Collaboration/Synergy Plan (2 pages)	
8.2.8. Publications	
8.2.9. Timeline (1 page)	
8.2.10. Current and Pending Support	
8.2.11. Research Environment (1 page)	
8.2.12. Descriptive Biography (Up to 2 pages)	
9. APPLICATION REVIEW	
9.1. REVIEW PROCESS	
9.2. Confidentiality of Review	
9.3. REVIEW CRITERIA	
10. KEY DATES	
11. AWARD ADMINISTRATION	
12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	
13. CONTACT INFORMATION	19
13.1. Helpdesk	19
13.2 SCIENTIFIC AND PROGRAMMATIC QUESTIONS	20

RFA VERSION HISTORY

Rev 6/21/19 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas
- Develop and implement the Texas Cancer Plan

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions; computational biology and analytic methods
- Childhood cancers
- Hepatocellular cancer

• Expand access to innovative clinical trials

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract world-class research scientists with distinguished professional careers to Texas universities and cancer research institutes to establish research programs that add research talent to the state. This award will support established academic leaders whose body of work has made an outstanding contribution to cancer research. Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the State of Texas.

The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment. However, special consideration will be given to candidates with research programs addressing CPRIT's priority areas for research. These include implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions, computational biology and analytic methods, childhood cancers, hepatocellular cancer, and expansion of access to innovative clinical trials.

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the State of Texas. This award honors outstanding senior investigators with proven track records of research accomplishments combined with excellence in leadership and teaching. All candidates should be recognized research or clinical investigators, held in the highest esteem by professional colleagues nationally and internationally, whose contributions have had a significant influence on their discipline and, likely, beyond. They must have clearly established themselves as exemplary faculty members with exceptional accomplishments in teaching and advising and/or basic, translational, population-based, or clinical cancer research activities. It is expected that the candidate will contribute significantly to and have a major impact on the institution's overall cancer research initiative. Candidates will be leaders capable

of initiating and developing creative ideas leading to novel solutions related to cancer detection, diagnosis, and/or treatment. They are also expected to maintain and lead a strong research group and have a stellar, high-impact publication portfolio, as well as continue to secure external funding. Furthermore, recipients will lead and inspire undergraduate and graduate students interested in pursuing research careers and will engage in collegial and collaborative relationships with others within and beyond their traditional discipline in an effort to expand the boundaries of cancer research.

Funding will be given for exceptional candidates who will continue to develop new research methods and techniques in the life, population-based, physical, engineering, or computational sciences and apply them to solving outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework.

Ideal candidates will have specific expertise in cancer-related areas needed to address an institutional priority. Candidates should be at the career level of a full professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience as vital metrics for guiding CPRIT's investment in that person's originality, insight, and potential for continued contribution. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

Applications nominating individuals who carry out patient-oriented research and who have demonstrated exceptional ability to lead innovative discovery campaigns through conduct of clinical trials are appropriate for this mechanism and encouraged.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, publications, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. INSTITUTIONAL COMMITMENT

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for

the recruitment of an Established Investigator should be complemented by a strong institutional commitment to the recruitment. The institutional commitment should be clearly documented in the application (see section 8.2.2) and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

5. FUNDING INFORMATION

This award is up to 5 years and is not renewable. Grant support will be awarded based upon the breadth and nature of the research program proposed. Grant funds of up to \$6,000,000 (total costs) for the 5-year period may be requested. Exceptions to this limit will be entertained only if there is compelling written justification. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years except under extraordinary circumstances with strong justification for a no-cost extension. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified. Scholars may request funds for travel for 2 project staff to attend CPRIT's conference.

Funds from this award mechanism may be used for salary support of this candidate but may not be used to construct or renovate laboratory space.

No annual limit on the number of grant application submissions by Institutions has been set.

Note the annual salary (also referred to as direct salary or institutional base salary) that an individual may be reimbursed from a CPRIT award for FY 2020 is limited to a maximum of \$200,000. In other words, an individual may request salary proportional to the percent of effort up to a maximum of \$200,000. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities.

Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

<u>Note:</u> Depending on the availability of funds, nominations submitted in response to this Request for Applications (RFA) during the current receipt period may be announced and awarded either in the current fiscal year (prior to August 31, 2020) or in the first quarter of the next fiscal year (starting September 1, 2020).

6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is
 interested in a given candidate, negotiations as to which institution will nominate him or
 her must be concluded before the nomination is made.
- There is no limit to the number of applications that an institution may submit during a review cycle.
- A candidate who has already accepted a position at the recruiting institution prior to the time that the Scientific Review Council reviews the candidate for a recruitment award is not eligible for a recruitment award, as an investment by CPRIT is obviously not necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's Academic Research program staff will notify the nominating institution of the Scientific Review Council's review decision following the Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's review decision but prior to the Oversight Committee's final approval, the institution does so at its own

- risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.
- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, **and reside in Texas for the duration of the appointment**. The candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate should hold an appointment at the rank of professor (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. The candidate must not reside in Texas at the time the application is submitted.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before

submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

7. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of Established Investigators award mechanism. Any nomination for the Recruitment of Established Investigators that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (Nominator) must create a user account in the system to start and submit an application. Furthermore, the Application Signing Official, who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Dependent upon available funding, applications will be accepted on a continuous basis throughout FY20. In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 PM central time on the 20th day of each month will be reviewed by the 15th day of the following month. For an application to be considered for review during the monthly cycle, that application must be submitted on or before 11:59 PM central time. In the event that the 20th falls on Saturday or Sunday, applications may be submitted on or before 11:59 PM central time the following Monday. CPRIT will not extend the submission deadline. During

periods when CPRIT does not receive an adequate number of applications, the review may be extended into the following month. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. For details, please refer to the *Instructions for Applicants* document that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in <u>section 6</u> will be administratively withdrawn without review.

8.2.1. Summary of Nomination (2,500 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

8.2.2. Institutional Commitment (3 pages)

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of an Established Investigator Faculty should be complemented by a strongly documented institutional commitment to the recruitment. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

The following guidelines should be followed when documenting the institutional commitment to the candidate:

• The institutional commitment should be clearly documented in the form of a letter signed by the applicant institution's president, provost, or appropriate dean and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

- Institutional Commitment as described above must be presented in a table (example below), that clearly identifies the salary amount, sources of salary, and any additional research support from institutional sources over the course of the CPRIT award.
- Include a brief job description for the candidate should recruitment be successful.
- Describe the institutional environment and any professional commitments to the
 candidate including but not limited to dedicated personnel, access to students, space
 assignment, and access to shared equipment, and discuss all other agreements between
 the institution and the candidate.
- Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research.
- Note that Texas law allows an institution of higher learning to use its federal indirect cost
 rate credit to comply with the requirement to demonstrate that it has an amount of funds
 equal to one-half of the CPRIT funding dedicated to the research that is the subject of the
 award (see section 12). However, a federal indirect cost rate credit cannot be used to
 demonstrate an institutional commitment to the candidate.

Example of an acceptable Institutional Commitment table:

Candidate's Name, Institutional Commitments						
	Year 1	Year 2	Year 3	Year 4	Year 5	
Salary/Benefits						
Research Support						
Administrative Support						
Moving Expenses						

Total =

Note: CPRIT acknowledges that the Institutional Commitments by category may change during the course of the award; however, the total financial commitment to the candidate must remain equal to or greater than 50% of the CPRIT award.

8.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department to which the candidate is being recruited. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research:

While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

8.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

8.2.5. Summary of Goals and Objectives (2,000 characters)

List goals and objectives to be achieved during this award. This section must be completed by the candidate.

8.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. Applications that do not contain this <u>signed</u> statement will be returned without review.

"I understand that I do not need to have made a commitment to *<nominating institution>* before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. I understand that requests to change the recruiting institution during the recruitment process are not allowed after the application is submitted to CPRIT."

8.2.7. Research Collaboration/Synergy Plan (2 pages)

Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research, such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research. Biographical sketches of collaborators established in the research collaborative plan must be uploaded as part of the application. This will be in addition to the 2-page synergy plan (see IFA).

8.2.8. Publications

Provide the 5 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

8.2.9. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.10. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted. Refer to the sample current and pending support document located in *Current*Funding Opportunities for Academic Research in CARS.

8.2.11. Research Environment (1 page)

Briefly describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

8.2.12. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award.

This section of the application must be prepared by the candidate. If the application is approved for funding, this section will be made publicly available on CPRIT's website.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 or more of these components; exceed the specified page, word, or budget limits; or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

9. APPLICATION REVIEW

9.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will review applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment.

Applications recommended by the Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions is sent to the nominator.

9.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, <u>Texas Administrative Code</u>, <u>Title 25</u>, <u>Chapters 701 to 703</u>.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, or a Scientific Review Council member.

Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of the Department of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.3. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is

the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from CPRIT and the host institution. It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his/her proposed research program, and his/her long-term contribution to and impact on the field of cancer research.

Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate made significant, transformative, and sustained contributions to basic, translational, clinical, or population-based cancer research? Is the candidate an established and nationally and/or internationally recognized leader in the field? Has the candidate demonstrated excellence in leadership and teaching? Has the candidate provided mentorship, inspiration, and/or professional training opportunities to junior scientists and students? Does the candidate have a strong record of research funding? Does the candidate have a publication history in high-impact journals? Does the candidate show evidence of collaborative interaction with others?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it expand the boundaries of cancer research beyond traditional methodology by incorporating novel and interdisciplinary techniques? Does the research program integrate with and/or increase collaborative research efforts and relationships at the nominating institution?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research program? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on maintaining and enhancing his or her research program?

10. **KEY DATES**

RFA

RFA Release

June 21, 2019

Application Receipt and Review Timeline

Application Receipt System opens 7 AM CT	Application Receipt	Anticipated Application Review	Application Closing Date
June 21, 2019	Continuous – dependent upon available funding	Monthly by the 15 th day of the month	June 20, 2020

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in <u>Texas Administrative Code</u>, <u>Title 25</u>, <u>Chapters 701 to 703</u>.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements CPRIT RFA R-20.1-REI Recruitment of Established Investigators

set forth in CPRIT's Administrative Rules, <u>Texas Administrative Code</u>, <u>Title 25</u>, <u>Chapters 701 to 703</u>.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. CPRIT requires funding acknowledgement on all print and visual materials, which are funded in whole or in part by CPRIT grants. Examples of print and visual materials include, but are not limited to publications, brochures, pamphlets, project websites, videos, and media materials. **Continuation of funding is contingent upon the timely receipt of these reports**. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703, for specific requirements regarding the demonstration of available funding.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Academic Research.

Tel: 512-305-8491

Email: <u>Help@CPRITGrants.org</u>

Website: www.cprit.texas.gov

Third Party Observer Reports



Cancer Prevention and Research Institute of Texas (CPRIT) Recruitment Review Panel - 20.7 (REC_20.7) Observation Report

Report No. 2020-02-13 REC_20.7 Program Name: Academic Research

Panel Name: Recruitment Review Panel - 20.7 (REC 20.7)

Panel Date: 02-13-2020 Report Date: 02-18-2020

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Recruitment Review Panel - 20.7 (REC_20.7) meeting. The meeting was chaired by Richard Kolodner and conducted by teleconference on February 13, 2020.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information:
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: One (1) panel chair, and Six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were no COI's present for this meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA Senior Partner

Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney



Cancer Prevention and Research Institute of Texas (CPRIT) Recruitment Review Panel - 20.8 (REC 20.8) Observation Report

Report No. 2020-03-12 REC_20.8

Program Name: Academic Research

Panel Name: Recruitment Review Panel - 20.8 (REC_20.8)

Panel Date: 03-12-2020 Report Date: 03-20-2020

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Recruitment Review Panel - 20.8 (REC_20.8) meeting. The meeting was chaired by Richard Kolodner and conducted by teleconference on March 12, 2020.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) COI's identified prior to and/or during the meeting. The COI's were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA Senior Partner

Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney



Cancer Prevention and Research Institute of Texas (CPRIT) 20.9 Recruitment Review Panel (REC_20.9) Observation Report

Report No. 2020-04-09 REC_20.9 Program Name: Academic Research

Panel Name: 20.9 Recruitment Review Panel (REC 20.9)

Panel Date: 04-09-2020 Report Date: 04-13-2020

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 20.9 Recruitment Review Panel (REC_20.9) meeting. The meeting was chaired by Richard Kolodner and conducted by teleconference on April 09. 2020.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information:
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair and five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) COI's identified prior to and/or during the meeting. The COI's were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA Senior Partner Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Academic Research Recruitment Cycles 20.7-9 Applications Academic Research Recruitment Cycles 20.7-9 Awards Announced at May 20, 2020, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycles 20.7-20.9 include *Recruitment of Rising Stars; Recruitment of Established Investigators;* and *Recruitment of First-Time, Tenure-Track Faculty Members*. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted		
Applications considered by the PIC and Oversight Committee					
RR200057	Gulio Draetta	The University of Texas M. D. Anderson Cancer Center	Margaret Tempero		
RR200072	W. P. Andrew Lee	The University of Texas Southwestern Medical Center	Myles Brown		
Applications not considered by the PIC or Oversight Committee					
RR200048	Mary Dickinson	Baylor College of Medicine	Margaret Tempero		
RR200068	W. P. Andrew Lee	The University of Texas Southwestern Medical Center	Carol Prives		

De-Identified Overall Evaluation Scores

Recruitment of Established Investigators

Academic Research Recruitment Cycles 20.7-20.9

Application ID	Final Overall Evaluation Score
RR200057*	1.2
RR200072*	1.5
RR200046*	2.0
RR200043*	2.8
aa	3.0
ab	3.2
ac	6.0

^{*=}Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd April 13, 2020

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@health.ucsd.edu

San Diego Branch

UC San Diego School of Medicine CMM-East / Rm 3058 9500 Gilman Dr - MC 0660 La Jolla, CA 92093-0660

T 858 534 7804 **F** 858 534 7750

The Honorable Dee Margo
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to dee@deemargo.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mayor Margo and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on February 13, 2020 (REC Cycle 20.7), March 12, 2020 (REC Cycle 20.8) and on April 9, 2020 (REC Cycle 20.9) to review the applications submitted to CPRIT under the Recruitment of Established Investigators, Recruitment of Rising Stars and Recruitment of First-Time Tenure Track Faculty Members.

The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation scores are stated for each grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is \$43,973,674.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research and exceptional potential for achieving future impact in basic, translational, population based or clinical research.

Sincerely yours,

Richard D. Kolodner

Attachment

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Rank	App ID	Mechanism	Candidate	Organization	Budget	Overall Score
1	RR200040	RFTFM	Van Nostrand, Eric	Baylor College of Medicine	\$2,000,000	1.0
2	RR200050	RFTFM	Cao, Junyue	Baylor College of Medicine	\$2,000,000	1.0
3	RR200039	RFTFM	Romero, Liela	Baylor University	\$2,000,000	1.2
4	RR200045	RFTFM	Hillman, Robert	The University of Texas M. D. Anderson Cancer Center	\$2,000,000	1.2
5	RR200057	REI	Felsher, Dean	The University of Texas M. D. Anderson Cancer Center	\$6,000,000	1.2
6	RR200072	REI	Wei, Wenyi	The University of Texas Southwestern Medical Center	\$6,000,000	1.5
7	RR200065	RFTFM	Lee, Jason	Baylor College of Medicine	\$2,000,000	1.8
8	RR200046	REI	Manning, Henry Charles	The University of Texas M. D. Anderson Cancer Center	\$5,000,000	2.0
9	RR200056	RRS	Fedirko, Veronika	The University of Texas M. D. Anderson Cancer Center	\$4,000,000	2.0
10	RR200054	RFTFM	Whisenant, Megan	The University of Texas Health Science Center at Houston	\$500,000	2.0
11	RR200070	RFTFM	Parker, Matthew	The University of Texas Southwestern Medical Center	\$2,000,000	2.0
12	RR200059	RFTFM	Fon Tracer, Klementina	Texas Tech University	\$1,400,000	2.2
13	RR200042	RRS	Wang, Ken	The University of Texas Southwestern Medical Center	\$4,000,000	2.7
14	RR200043	REI	Lele, Tanmay	Texas A&M Engineering Experiment Station	\$5,073,674	2.8

REI- Recruitment of Established Investigators RRS- Recruitment of Rising Stars RFTFM- Recruitment of First-Time, Tenure Track Faculty Members



CEO Affidavit Supporting Information

FY 2020 Cycles 20.7 through 20.9 Recruitment of First-Time, Tenure-Track Faculty Members

Request for Applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-20.1-RFT

Recruitment of First-Time Tenure-Track Faculty Members

Please also refer to the Instructions for Applicants document, which will be posted on June 21, 2019

Application Receipt Dates:

June 21, 2019-June 20, 2020

FY2020

Fiscal Year Award Period September 1, 2019-August 31, 2020

TABLE OF CONTENTS

1. ABOUT CPRIT	4
1.1. ACADEMIC RESEARCH PROGRAM PRIORITIES	4
2. RATIONALE	5
3. RECRUITMENT OBJECTIVES	5
4. INSTITUTIONAL COMMITMENT	
5. FUNDING INFORMATION	
6. ELIGIBILITY	
7. RESUBMISSION POLICY	
8. RESPONDING TO THIS RFA	
8.1. Application Submission Guidelines	
8.2. APPLICATION COMPONENTS	
8.2.1. Summary of Nomination (2,000 characters)	
8.2.2. Institutional Commitment (3 pages)	
8.2.3. Letter of Support from Department Chair (1 page)	
8.2.4. Curriculum Vitae (CV)	13
8.2.5. Summary of Goals and Objectives (2,000 characters)	
8.2.6. Research (4 pages)	
8.2.7. Research Collaboration/Synergy Plan (2 pages)	
8.2.8. Publications	
8.2.9. Timeline (1 page)	
8.2.10. Current and Pending Support	
8.2.11. Letters of Recommendation	
8.2.12. Research Environment (1 page)	
8.2.13. Descriptive Biography (Up to 2 pages)	
9.1. REVIEW PROCESS	
9.1.1. Confidentiality of Review	
9.2. Review Criteria	
10. KEY DATES	
11. AWARD ADMINISTRATION	
12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	
13. CONTACT INFORMATION	
13.1. HELPDESK	
13.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	
13.2. SCIENTIFIC AND I ROURAWINATIC QUESTIONS	∠1

RFA VERSION HISTORY

Rev 6/21/19 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas
- Develop and implement the Texas Cancer Plan

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions
- Computational biology and analytic methods
- Childhood cancers
- Hepatocellular cancer

• Expand access to innovative clinical trials

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract very promising investigators who are pursuing their first faculty appointment at the level of assistant professor (**first-time**, **tenure-track faculty members**). These individuals must have demonstrated academic excellence, innovation during predoctoral and/or postdoctoral research training, commitment to pursuing cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research. Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the State of Texas.

The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment; however, special consideration will be given to candidates with research programs addressing CPRIT's priority areas for research. These include implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions, computational biology and analytic methods, childhood cancers, hepatocellular cancer, and expansion of access to innovative clinical trials.

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the State of Texas. All candidates are expected to have completed their doctoral and fellowship training and to have clearly demonstrated truly superior ability as evidenced by their accomplishments during training, proposed research plan, publication record, and letters of recommendation. This CPRIT-supported initiative is designed to enhance innovative programs of excellence by providing research support for promising, early-stage investigators seeking their first tenure-track position.

CPRIT will provide start-up funding for newly independent investigators, with the goal of augmenting and expanding the institution's efforts in cancer research. Candidates will be expected to develop research projects within the sponsoring institution. Projects should be appropriate for a newly independent investigator and should foster the development of preliminary data that can be used to prepare applications for future independent research project grants to further both the investigator's research career and the CPRIT mission. The institution will be expected to work with each newly recruited research faculty member to design and execute a faculty career development plan consistent with his or her research emphasis. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

Applications nominating individuals who are well prepared to pursue careers in patient-oriented research and who have demonstrated exceptional potential to lead innovative discovery campaigns through conduct of clinical trials are appropriate for this mechanism and encouraged.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, publications, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. INSTITUTIONAL COMMITMENT

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a First-Time Tenure-Track Faculty should therefore be complemented by a strong institutional commitment to the candidate's career development that includes financial commitments that are in addition to the CPRIT award. The institutional commitment should be clearly documented in the application (see section 8.2.2) and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate for his or her research program by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

5. FUNDING INFORMATION

This award is up to 5 years and is not renewable, although individuals may apply for other future CPRIT funding as appropriate. Grant funds of up to \$2,000,000 (total costs) for the 5-year period may be requested. Funding is to be used by the candidate to support his or her research program. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years except under extraordinary circumstances with strong justification for a no-cost extension. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified. Scholars may request funds for travel for 2 project staff to attend CPRIT's conference.

Funds from this CPRIT award may not be used for salary support of this candidate or to construct or renovate laboratory space.

No annual limit on the number of grant application submissions by Institutions has been set.

<u>Note:</u> Depending on the availability of funds, nominations submitted in response to this Request for Applications (RFA) during the current receipt period may be announced and awarded either in the current fiscal year (prior to August 31, 2020) or in the first quarter of the next fiscal year (starting September 1, 2020).

6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is
 interested in a given candidate, negotiations as to which institution will nominate him or
 her must be concluded before the nomination is made.

- There is no limit to the number of applications that an institution may submit during a review cycle.
- A candidate who has already accepted a position as assistant professor tenure track at the recruiting institution prior to the time that the Scientific Review Council reviews the candidate for a recruitment award is not eligible for a recruitment award, as an investment by CPRIT is obviously not necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's Academic Research program staff will notify the nominating institution of the Scientific Review Council's review decision following the Scientific Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's review decision but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.
- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, **and reside in Texas for the duration of the appointment.** The candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate must <u>not</u> hold an appointment at the rank of assistant professor or above (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. Candidates holding non-tenure-track appointments at the rank of assistant professor are <u>not</u> eligible for this award. Examples of such appointments include research assistant professor, adjunct research assistant professor, assistant professor (non-tenure track).
- The candidate <u>may or may not</u> reside in Texas at the time the application is submitted and may be nominated for a faculty position at the Texas institution where he or she is completing postdoctoral training.
- Applications nominating a candidate for a faculty position at the Texas institution where he or she is completing postdoctoral training that do not clearly demonstrate a

- subsequent career pathway to independence for the candidate will not be looked upon with favor.
- Successful candidates will be offered tenure-track academic positions at the rank of assistant professor.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

7. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of First-Time, Tenure-Track Faculty Members award mechanism. Any nomination for the Recruitment of First-Time, Tenure-Track

Faculty Members that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (Nominator) must create a user account in the system to start and submit an application. Furthermore, the Application Signing Official, who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Dependent upon available funding, applications will be accepted on a continuous basis throughout FY20. In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 PM central time on the 20th day of each month will be reviewed by the 15th day of the following month. For an application to be considered for review during the monthly cycle, that application must be submitted on or before 11:59 PM central time. In the event that the 20th falls on Saturday or Sunday, applications may be submitted on or before 11:59 PM central time the following Monday. CPRIT will not extend the submission deadline. During periods when CPRIT does not receive an adequate number of applications, the review may be extended into the following month. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. For details, please refer to the *Instructions for Applicants* document that will be available when the application receipt system opens. Submissions that are

missing 1 or more components or do not meet the eligibility requirements listed in <u>section 6</u> will be administratively withdrawn without review.

8.2.1. Summary of Nomination (2,000 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

8.2.2. Institutional Commitment (3 pages)

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a First-Time Tenure-Track Faculty should therefore be complemented by a strongly documented institutional commitment to the candidate's career development that includes financial commitments that are in addition to the CPRIT award.

The following guidelines should be followed when documenting the institutional commitment to the candidate:

- The institutional commitment should be clearly documented in the form of a letter signed by the applicant institution's president, provost, or appropriate dean and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.
- Institutional Commitment as described above must be presented in a table (example below), that clearly identifies the salary amount, sources of salary, and any additional research support from institutional sources over the course of the CPRIT award.
- Include a brief job description for the candidate should recruitment be successful.
- Describe the institutional environment and any professional commitments to the
 candidate including but not limited to dedicated personnel, access to students, space
 assignment, and access to shared equipment, and discuss all other agreements between
 the institution and the candidate.

- Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research.
- Note that Texas law allows an institution of higher learning to use its federal indirect cost
 rate credit to comply with the requirement to demonstrate that it has an amount of funds
 equal to one-half of the CPRIT funding dedicated to the research that is the subject of the
 award (see section 12). However, a federal indirect cost rate credit cannot be used to
 demonstrate an institutional commitment to the candidate.

Example of an acceptable Institutional Commitment table:

Candidates Name, Institutional Commitments					
	Year 1	Year 2	Year 3	Year 4	Year 5
Salary/Benefits					
Research Support					
Administrative Support					
Moving Expenses					

Total =

Note: CPRIT acknowledges that the Institutional Commitments by category may change during the course of the award; however, the total financial commitment to the candidate must remain equal to or greater than 50% of the CPRIT award.

8.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department to which the candidate is being recruited. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of the nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research:

While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

The letter of support from the department chair <u>must</u> also do the following:

- 1. Describe how the candidate will be independent and autonomous in developing his or her research program at the institution;
- 2. Present a plan for mentoring that includes the design and execution of a faculty career development plan for the candidate.

8.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate. Only articles that have been published or that have been accepted for publication ("in press") should be cited.

8.2.5. Summary of Goals and Objectives (2,000 characters)

List goals and objectives to be achieved during this award. This section must be completed by the candidate.

8.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. Applications that do not contain this <u>signed</u> statement will be returned without review.

"I understand that I do not need to have made a commitment to *<nominating institution>* before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. I understand that requests to change the recruiting institution during the recruitment process are not allowed after the application is submitted to CPRIT.

8.2.7. Research Collaboration/Synergy Plan (2 pages)

Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research, such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research. Biographical sketches of collaborators established in the research collaborative plan must be uploaded as part of the application. This will be in addition to the 2-page synergy plan (see IFA).

8.2.8. Publications

Provide the 3 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

8.2.9. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.10. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted. Refer to the sample current and pending support document located in *Current*Funding Opportunities for Academic Research in CARS.

8.2.11. Letters of Recommendation

Provide 3 letters of recommendation from individuals who are in a position to detail the candidate's academic and scientific research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research.

8.2.12. Research Environment (1 page)

Clearly and concisely describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

8.2.13. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award.

This section of the application must be prepared by the candidate. If the application is approved for funding, this section will be made publicly available on CPRIT's website.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 or more of these components; exceed the specified page, word, or budget limits; or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

9. APPLICATION REVIEW

9.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will review applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications recommended by the Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight

Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions is sent to the nominator.

9.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b). Individuals directly involved with the review process operate under strict conflict-of-interest

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters

prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

701 to 703.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, or a Scientific Review Council member.

Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of the Department of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of

this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from both CPRIT and the host institution.

It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have reasonable expectation that the recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his or her proposed research program, and his or her long-term contribution to and impact on the field of cancer research. Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate demonstrated academic excellence? Has the candidate received excellent predoctoral and postdoctoral training? Does the candidate show exceptional potential for achieving future impact on basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated a commitment to cancer research? Has the candidate demonstrated independence or the potential for independence?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will the proposed research generate preliminary data that can be used for the preparation of applications for future independent research project grants?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Letters of Recommendation: Do the letters of recommendation detail the candidate's academic and clinical research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on growing his or her research? Has the institution identified a mentor who will design and execute a faculty career development plan for the candidate?

10. KEY DATES

RFA

RFA Release

June 21, 2019

Application Receipt and Review Timeline

Application Receipt System opens 7 AM CT	Application Receipt	Anticipated Application Review	Application Closing Date
June 21, 2019	Continuous – dependent upon available funding	Monthly by the 15 th day of the month	June 20, 2020

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. CPRIT requires funding acknowledgement on all print and visual materials, which are funded in whole or in part by CPRIT grants. Examples of print and visual materials include, but are not limited to publications, brochures, pamphlets, project websites, videos and media materials. **Continuation of funding is contingent upon the timely receipt of these reports.** Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703, for specific requirements regarding the demonstration of available funding.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Academic Research.

Tel: 512-305-8491

Email: <u>Help@CPRITGrants.org</u>

Website: www.cprit.texas.gov

Third Party Observer Reports



Cancer Prevention and Research Institute of Texas (CPRIT) Recruitment Review Panel - 20.7 (REC_20.7) Observation Report

Report No. 2020-02-13 REC_20.7 Program Name: Academic Research

Panel Name: Recruitment Review Panel - 20.7 (REC 20.7)

Panel Date: 02-13-2020 Report Date: 02-18-2020

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Recruitment Review Panel - 20.7 (REC_20.7) meeting. The meeting was chaired by Richard Kolodner and conducted by teleconference on February 13, 2020.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information:
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: One (1) panel chair, and Six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were no COI's present for this meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA Senior Partner

Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney



Cancer Prevention and Research Institute of Texas (CPRIT) Recruitment Review Panel - 20.8 (REC 20.8) Observation Report

Report No. 2020-03-12 REC_20.8

Program Name: Academic Research

Panel Name: Recruitment Review Panel - 20.8 (REC_20.8)

Panel Date: 03-12-2020 Report Date: 03-20-2020

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Recruitment Review Panel - 20.8 (REC_20.8) meeting. The meeting was chaired by Richard Kolodner and conducted by teleconference on March 12, 2020.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) COI's identified prior to and/or during the meeting. The COI's were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA Senior Partner

Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney



Cancer Prevention and Research Institute of Texas (CPRIT) 20.9 Recruitment Review Panel (REC_20.9) Observation Report

Report No. 2020-04-09 REC_20.9 Program Name: Academic Research

Panel Name: 20.9 Recruitment Review Panel (REC 20.9)

Panel Date: 04-09-2020 Report Date: 04-13-2020

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 20.9 Recruitment Review Panel (REC_20.9) meeting. The meeting was chaired by Richard Kolodner and conducted by teleconference on April 09. 2020.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information:
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair and five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) COI's identified prior to and/or during the meeting. The COI's were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA Senior Partner Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Academic Research Recruitment Cycles 20.7-9 Applications Academic Research Recruitment Cycles 20.7-9 Awards Announced at May 20, 2020, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycles 20.7-20.9 include *Recruitment of Rising Stars; Recruitment of Established Investigators;* and *Recruitment of First-Time, Tenure-Track Faculty Members*. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted	
Applications considered by the PIC and Oversight Committee				
RR200057	Gulio Draetta	The University of Texas M. D. Anderson Cancer Center	Margaret Tempero	
RR200072	W. P. Andrew Lee	The University of Texas Southwestern Medical Center	Myles Brown	
Applications not considered by the PIC or Oversight Committee				
RR200048	Mary Dickinson	Baylor College of Medicine	Margaret Tempero	
RR200068	W. P. Andrew Lee	The University of Texas Southwestern Medical Center	Carol Prives	

De-Identified Overall Evaluation Scores

Recruitment of First-Time, Tenure-Track Faculty Members

Academic Research Recruitment Cycles 20.7-20.9

Application ID	Final Overall Evaluation Score
RR200040*	1.0
RR200050*1	1.0
RR200039*	1.2
RR200045*	1.2
RR200065*	1.8
RR200070*	2.0
RR200054*	2.0
RR200059*	2.2
ca	3.0
cb	3.2
сс	3.5
cd	3.5
ce	3.8
cf	4.0

¹ RR200050 was withdrawn by the applicant after the Scientific Review Council recommended the application to the Program Integration Committee (PIC). Therefore, the PIC did not consider this application during its meeting on May 5, 2020.

^{*=}Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd April 13, 2020

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@health.ucsd.edu

San Diego Branch

UC San Diego School of Medicine CMM-East / Rm 3058 9500 Gilman Dr - MC 0660 La Jolla, CA 92093-0660

T 858 534 7804 **F** 858 534 7750

The Honorable Dee Margo
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to dee@deemargo.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mayor Margo and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on February 13, 2020 (REC Cycle 20.7), March 12, 2020 (REC Cycle 20.8) and on April 9, 2020 (REC Cycle 20.9) to review the applications submitted to CPRIT under the Recruitment of Established Investigators, Recruitment of Rising Stars and Recruitment of First-Time Tenure Track Faculty Members.

The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation scores are stated for each grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is \$43,973,674.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research and exceptional potential for achieving future impact in basic, translational, population based or clinical research.

Sincerely yours,

Richard D. Kolodner

Attachment

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Rank	App ID	Mechanism	Candidate	Organization	Budget	Overall Score
1	RR200040	RFTFM	Van Nostrand, Eric	Baylor College of Medicine	\$2,000,000	1.0
2	RR200050	RFTFM	Cao, Junyue	Baylor College of Medicine	\$2,000,000	1.0
3	RR200039	RFTFM	Romero, Liela	Baylor University	\$2,000,000	1.2
4	RR200045	RFTFM	Hillman, Robert	The University of Texas M. D. Anderson Cancer Center	\$2,000,000	1.2
5	RR200057	REI	Felsher, Dean	The University of Texas M. D. Anderson Cancer Center	\$6,000,000	1.2
6	RR200072	REI	Wei, Wenyi	The University of Texas Southwestern Medical Center	\$6,000,000	1.5
7	RR200065	RFTFM	Lee, Jason	Baylor College of Medicine	\$2,000,000	1.8
8	RR200046	REI	Manning, Henry Charles	The University of Texas M. D. Anderson Cancer Center	\$5,000,000	2.0
9	RR200056	RRS	Fedirko, Veronika	The University of Texas M. D. Anderson Cancer Center	\$4,000,000	2.0
10	RR200054	RFTFM	Whisenant, Megan	The University of Texas Health Science Center at Houston	\$500,000	2.0
11	RR200070	RFTFM	Parker, Matthew	The University of Texas Southwestern Medical Center	\$2,000,000	2.0
12	RR200059	RFTFM	Fon Tracer, Klementina	Texas Tech University	\$1,400,000	2.2
13	RR200042	RRS	Wang, Ken	The University of Texas Southwestern Medical Center	\$4,000,000	2.7
14	RR200043	REI	Lele, Tanmay	Texas A&M Engineering Experiment Station	\$5,073,674	2.8

REI- Recruitment of Established Investigators RRS- Recruitment of Rising Stars RFTFM- Recruitment of First-Time, Tenure Track Faculty Members



CEO Affidavit Supporting Information

FY 2020 Cycles 20.7 through 20.9 Recruitment of Rising Stars

Request for Applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-20.1-RRS

Recruitment of Rising Stars

Please also refer to the Instructions for Applicants document, which will be posted on June 21, 2019

Application Receipt Dates:

June 21, 2019-June 20, 2020

FY 2020

Fiscal Year Award Period September 1, 2019-August 31, 2020

TABLE OF CONTENTS

1. ABOUT CPRIT	4
1.1. ACADEMIC RESEARCH PROGRAM PRIORITIES	4
2. RATIONALE	5
3. RECRUITMENT OBJECTIVES	5
4. INSTITUTIONAL COMMITMENT	6
5. FUNDING INFORMATION	7
6. ELIGIBILITY	
7. RESUBMISSION POLICY	
8. RESPONDING TO THIS RFA	
8.1. Application Submission Guidelines	
8.2. APPLICATION COMPONENTS	
8.2.1. Summary of Nomination (2,000 characters)	
8.2.2. Institutional Commitment (3 pages)	
8.2.3. Letter of Support from Department Chair (1 page)	
8.2.4. Curriculum Vitae (CV)	
8.2.5. Summary of Goals and Objectives (2,000 characters)	
8.2.6. Research (4 pages)	
8.2.7. Research Collaboration/Synergy Plan (2 pages)	14
8.2.8. Publications	
8.2.9. Timeline (1 page)	
8.2.10. Current and Pending Support	
8.2.11. Research Environment (1 page)	
8.2.12. Descriptive Biography (Up to 2 pages)	
9. APPLICATION REVIEW	
9.1. REVIEW PROCESS	
9.1.1. Confidentiality of Review	
9.2. REVIEW CRITERIA	
10. KEY DATES	
11. AWARD ADMINISTRATION	
12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	
13. CONTACT INFORMATION	
13.1. Helpdesk	
13.2. SCIENTIFIC AND PROGRAMMATIC OUESTIONS	19

RFA VERSION HISTORY

Rev 6/21/19 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas
- Develop and implement the Texas Cancer Plan

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions
- Computational biology and analytic methods
- Childhood cancers
- Hepatocellular cancer

• Expand access to innovative clinical trials

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract individuals whose work has outstanding merit, who show a marked capacity for self-direction, and who demonstrate the promise for continued and enhanced contributions to the field of cancer research ("Rising Stars"). Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the State of Texas.

The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment. However, special consideration will be given to candidates with research programs addressing CPRIT's priority areas for research. These include implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions, computational biology and analytic methods, childhood cancers, hepatocellular cancer, and expansion of access to innovative clinical trials.

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the State of Texas. Having already demonstrated extraordinary accomplishments during their initial years of independent research, Rising Stars represent a unique blend of scholastic aptitude, scientific rigor, and commitment to exploring transformational research through the development of creative ideas with high potential.

Candidates who have not historically worked in cancer research but are proposing creative hypotheses and research plans for this field are encouraged to apply. Similarly, candidates pursuing original and potentially high-impact basic science programs that have the potential to be translated toward clinical investigations or provide "proof of principle" are also encouraged to apply. It is expected that the candidate will contribute significantly to and have a major impact on the institution's overall cancer research initiative. Funding will be given for exceptional

candidates who will continue to develop new research methods and techniques in the life, population-based, physical, engineering, or computational sciences and apply them to solving outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework.

Ideal candidates will have specific expertise in cancer-related areas needed to address an institutional priority. Candidates are expected to be approximately at the career level of a late assistant/early associate professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience vital metrics for guiding CPRIT's investment in that person's originality, insight, and potential for continued contribution. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

Applications nominating individuals who carry out patient-oriented research and who have demonstrated exceptional ability to lead innovative discovery campaigns through conduct of clinical trials are appropriate for this mechanism and encouraged.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, publications, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. INSTITUTIONAL COMMITMENT

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a Rising Star should be complemented by a strong institutional commitment to the recruitment. The institutional commitment should be clearly documented in the application (see section 8.2.2) and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

5. FUNDING INFORMATION

This is a 5-year award and is not renewable. Grant funds of up to \$4,000,000 (total costs) over a 5-year period may be requested. Exceptions to this limit will be entertained only if there is compelling written justification. Annual allocations of this award are at the discretion of the awardee as long as the total award does not exceed \$4,000,000. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years except under extraordinary circumstances with strong justification for a nocost extension. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified. Scholars may request funds for travel for 2 project staff to attend CPRIT's conference.

Funds from this award mechanism may be used for salary support of this candidate but may not be used to construct or renovate laboratory space.

No annual limit on the number of grant application submissions by Institutions has been set.

Note the annual salary (also referred to as direct salary or institutional base salary) that an individual may be reimbursed from a CPRIT award for FY 2020 is limited to a maximum of \$200,000. In other words, an individual may request salary proportional to the percent of effort up to a maximum of \$200,000. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

<u>Note:</u> Depending on the availability of funds, nominations submitted in response to this Request for Applications (RFA) during the current receipt period may be announced and awarded either in the current fiscal year (prior to August 31, 2020) or in the first quarter of the next fiscal year (starting September 1, 2020).

6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is
 interested in a given candidate, negotiations as to which institution will nominate him or
 her must be concluded before the nomination is made.
- There is no limit to the number of applications that an institution may submit during a review cycle.
- A candidate who has already accepted a position at the recruiting institution prior to the time that the Scientific Review Council reviews the candidate for a recruitment award is not eligible for a recruitment award, as an investment by CPRIT is obviously not necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's Academic Research program staff will notify the nominating institution of the Scientific Review Council's review decision following the Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's review decision but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.
- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and reside in Texas for the duration of the appointment. The candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate should hold an appointment at the rank of assistant or associate professor tenure track or tenured (or equivalent) at an accredited

- academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. The candidate <u>must not</u> reside in Texas at the time the application is submitted.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

7. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of Rising Stars award mechanism. Any nomination for the Recruitment of Rising Stars that was previously submitted to CPRIT and

reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (Nominator) must create a user account in the system to start and submit an application. Furthermore, the Application Signing Official, who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Dependent upon available funding, applications will be accepted on a continuous basis throughout FY20. In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 PM central time on the 20th day of each month will be reviewed by the 15th day of the following month. For an application to be considered for review during the monthly cycle, that application must be submitted on or before 11:59 PM central time. In the event that the 20th falls on Saturday or Sunday, applications may be submitted on or before 11:59 PM central time the following Monday. CPRIT will not extend the submission deadline. During periods when CPRIT does not receive an adequate number of applications, the review may be extended into the following month. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. For details, please refer to the *Instructions for Applicants* document that will be available when the application receipt system opens.

Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 6 will be administratively withdrawn without review.

8.2.1. Summary of Nomination (2,000 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

8.2.2. Institutional Commitment (3 pages)

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a Rising Star should be complemented by a strongly documented institutional commitment to the recruitment. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

The following guidelines should be followed when documenting the institutional commitment to the candidate:

- The institutional commitment should be clearly documented in the form of a letter signed by the applicant institution's president, provost, or appropriate dean and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.
- Institutional Commitment as described above must be presented in a table (example below), that clearly identifies the salary amount, sources of salary, and any additional research support from institutional sources over the course of the CPRIT award.
- Include a brief job description for the candidate should recruitment be successful.
- Describe the institutional environment and any professional commitments to the candidate including but not limited to dedicated personnel, access to students, space

- assignment, and access to shared equipment, and discuss all other agreements between the institution and the candidate.
- Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research.
- Note that Texas law allows an institution of higher learning to use its federal indirect cost
 rate credit to comply with the requirement to demonstrate that it has an amount of funds
 equal to one-half of the CPRIT funding dedicated to the research that is the subject of the
 award (see section 12). However, a federal indirect cost rate credit cannot be used to
 demonstrate an institutional commitment to the candidate.

Example of an acceptable Institutional Commitment table:

Candidate's Name, Institutional Commitments					
	Year 1	Year 2	Year 3	Year 4	Year 5
Salary/Benefits					
Research Support					
Administrative Support					
Moving Expenses					

Total =

Note: CPRIT acknowledges that the Institutional Commitments by category may change during the course of the award; however, the total financial commitment to the candidate must remain equal to or greater than 50% of the CPRIT award.

8.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department to which the candidate is being recruited. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of the nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research:

While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

8.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

8.2.5. Summary of Goals and Objectives (2,000 characters)

List goals and objectives to be achieved during this award. This section must be completed by the candidate.

8.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. Applications that do not contain this <u>signed</u> statement will be returned without review.

"I understand that I do not need to have made a commitment to *<nominating institution>* before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. I understand that requests to change the recruiting institution during the recruitment process are not allowed after the application is submitted to CPRIT."

8.2.7. Research Collaboration/Synergy Plan (2 pages)

Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research, such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research. Biographical sketches of collaborators established in the research collaborative plan must be uploaded as part of the application. This will be in addition to the 2-page synergy plan (see IFA).

8.2.8. Publications

Provide the 5 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

8.2.9. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.10. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.11. Research Environment (1 page)

Briefly describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

8.2.12. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award.

This section of the application must be prepared by the candidate. If the application is approved for funding, this section will be made publicly available on CPRIT's website.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 or more of these components; exceed the specified page, word, or budget limits; or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

9. APPLICATION REVIEW

9.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will review applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications recommended by the Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions is sent to the nominator.

9.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, <u>Texas Administrative Code</u>, <u>Title 25</u>, <u>Chapters 701 to 703</u>.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: An Oversight Committee member, a PIC member, or a Scientific Review Council member.

Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of the Department of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from CPRIT and the host institution. It is not necessary that a candidate agree to accept the recruitment offer at the time

an application is submitted. However, applicant institutions should have reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his/her proposed research program, and his/her long-term contribution to and impact on the field of cancer research.

Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate demonstrated extraordinary accomplishments during his or her initial years of independent research? Does the candidate show promise of making important contributions with significant impact to basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated strong self-direction, motivation, and commitment for transformative cancer research?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will it expand the boundaries of cancer research beyond traditional methodology by incorporating novel and interdisciplinary techniques?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on maintaining and enhancing his or her research program? Will the candidate be provided with adequate professional development opportunities to grow as a leader?

10. KEY DATES

RFA

RFA Release June 21, 2019

Application Receipt and Review Timeline

Application Receipt System opens 7 AM CT	Application Receipt	Anticipated Application Review	Application Closing Date	
June 21, 2019	Continuous – dependent upon available funding	Monthly by the 15 th day of the month	June 20, 2020	

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in <u>Texas Administrative Code</u>, <u>Title 25</u>, <u>Chapters 701 to 703</u>.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, <u>Texas Administrative Code</u>, <u>Title 25</u>, <u>Chapters 701 to 703</u>.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. CPRIT requires funding acknowledgement on all print and visual materials that are funded in whole or in part by CPRIT grants. Examples of print and visual materials include, but are not limited to, publications, brochures, pamphlets, project websites, videos, and media materials. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant

award costs and may result in the termination of the award contract. Forms and instructions will

be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must

demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to

the research that is the subject of the award. The demonstration of available matching funds must

be made at the time the award contract is executed and annually thereafter, not when the

application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules,

Texas Administrative Code, Title 25, Chapters 701 to 703, for specific requirements regarding

the demonstration of available funding.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of

applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff

members are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding

opportunities, should be directed to the CPRIT Senior Program Manager for Academic Research.

Tel: 512-305-8491

Email: <u>Help@CPRITGrants.org</u>

Website: www.cprit.texas.gov

Third Party Observer Reports



Cancer Prevention and Research Institute of Texas (CPRIT) Recruitment Review Panel - 20.7 (REC_20.7) Observation Report

Report No. 2020-02-13 REC_20.7 Program Name: Academic Research

Panel Name: Recruitment Review Panel - 20.7 (REC 20.7)

Panel Date: 02-13-2020 Report Date: 02-18-2020

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Recruitment Review Panel - 20.7 (REC_20.7) meeting. The meeting was chaired by Richard Kolodner and conducted by teleconference on February 13, 2020.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information:
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: One (1) panel chair, and Six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were no COI's present for this meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA Senior Partner

Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney



Cancer Prevention and Research Institute of Texas (CPRIT) Recruitment Review Panel - 20.8 (REC 20.8) Observation Report

Report No. 2020-03-12 REC_20.8

Program Name: Academic Research

Panel Name: Recruitment Review Panel - 20.8 (REC_20.8)

Panel Date: 03-12-2020 Report Date: 03-20-2020

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Recruitment Review Panel - 20.8 (REC_20.8) meeting. The meeting was chaired by Richard Kolodner and conducted by teleconference on March 12, 2020.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) COI's identified prior to and/or during the meeting. The COI's were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA Senior Partner

Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney



Cancer Prevention and Research Institute of Texas (CPRIT) 20.9 Recruitment Review Panel (REC_20.9) Observation Report

Report No. 2020-04-09 REC_20.9 Program Name: Academic Research

Panel Name: 20.9 Recruitment Review Panel (REC 20.9)

Panel Date: 04-09-2020 Report Date: 04-13-2020

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 20.9 Recruitment Review Panel (REC_20.9) meeting. The meeting was chaired by Richard Kolodner and conducted by teleconference on April 09. 2020.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information:
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair and five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) COI's identified prior to and/or during the meeting. The COI's were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA Senior Partner Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Academic Research Recruitment Cycles 20.7-9 Applications Academic Research Recruitment Cycles 20.7-9 Awards Announced at May 20, 2020, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycles 20.7-20.9 include *Recruitment of Rising Stars; Recruitment of Established Investigators;* and *Recruitment of First-Time, Tenure-Track Faculty Members*. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted			
Applications considered by the PIC and Oversight Committee						
RR200057	Gulio Draetta	The University of Texas M. D. Anderson Cancer Center	Margaret Tempero			
RR200072	W. P. Andrew Lee	The University of Texas Southwestern Medical Center	Myles Brown			
Applications not considered by the PIC or Oversight Committee						
RR200048	Mary Dickinson	Baylor College of Medicine	Margaret Tempero			
RR200068 W. P. Andrew Lee		The University of Texas Southwestern Medical Center	Carol Prives			

De-Identified Overall Evaluation Scores

Recruitment of Rising Stars

Academic Research Recruitment Cycles 20.7-20.9

Application ID	Final Overall Evaluation Score
RR200056*	2.0
RR200042*	2.7
ba	3.8
bb	4.0
bc	4.2

^{*=}Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd April 13, 2020

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@health.ucsd.edu

San Diego Branch

UC San Diego School of Medicine CMM-East / Rm 3058 9500 Gilman Dr - MC 0660 La Jolla, CA 92093-0660

T 858 534 7804 **F** 858 534 7750

The Honorable Dee Margo
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to dee@deemargo.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mayor Margo and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on February 13, 2020 (REC Cycle 20.7), March 12, 2020 (REC Cycle 20.8) and on April 9, 2020 (REC Cycle 20.9) to review the applications submitted to CPRIT under the Recruitment of Established Investigators, Recruitment of Rising Stars and Recruitment of First-Time Tenure Track Faculty Members.

The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation scores are stated for each grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is \$43,973,674.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research and exceptional potential for achieving future impact in basic, translational, population based or clinical research.

Sincerely yours,

Richard D. Kolodner

Attachment

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Rank	App ID	Mechanism	Candidate	Organization	Budget	Overall Score
1	RR200040	RFTFM	Van Nostrand, Eric	Baylor College of Medicine	\$2,000,000	1.0
2	RR200050	RFTFM	Cao, Junyue	Baylor College of Medicine	\$2,000,000	1.0
3	RR200039	RFTFM	Romero, Liela	Baylor University	\$2,000,000	1.2
4	RR200045	RFTFM	Hillman, Robert	The University of Texas M. D. Anderson Cancer Center	\$2,000,000	1.2
5	RR200057	REI	Felsher, Dean	The University of Texas M. D. Anderson Cancer Center	\$6,000,000	1.2
6	RR200072	REI	Wei, Wenyi	The University of Texas Southwestern Medical Center	\$6,000,000	1.5
7	RR200065	RFTFM	Lee, Jason	Baylor College of Medicine	\$2,000,000	1.8
8	RR200046	REI	Manning, Henry Charles	The University of Texas M. D. Anderson Cancer Center	\$5,000,000	2.0
9	RR200056	RRS	Fedirko, Veronika	The University of Texas M. D. Anderson Cancer Center	\$4,000,000	2.0
10	RR200054	RFTFM	Whisenant, Megan	The University of Texas Health Science Center at Houston	\$500,000	2.0
11	RR200070	RFTFM	Parker, Matthew	The University of Texas Southwestern Medical Center	\$2,000,000	2.0
12	RR200059	RFTFM	Fon Tracer, Klementina	Texas Tech University	\$1,400,000	2.2
13	RR200042	RRS	Wang, Ken	The University of Texas Southwestern Medical Center	\$4,000,000	2.7
14	RR200043	REI	Lele, Tanmay	Texas A&M Engineering Experiment Station	\$5,073,674	2.8

REI- Recruitment of Established Investigators RRS- Recruitment of Rising Stars RFTFM- Recruitment of First-Time, Tenure Track Faculty Members



CEO AFFIDAVIT Application DP200034 Company Relocation Product Development Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Company Relocation Product Development Research Awards* Request for Applications (RFA). CPRIT received 16 applications in response to this RFA. This application was assigned to the product development panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

On November 18, 2019, I notified the Oversight Committee members that I granted members of the Product Development Review Council (PDRC) a waiver from the general prohibition against communicating with grant applicants, pursuant to Texas Administrative Code § 702.19(e). A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

On January 13, 2020, the PDRC took no action on this application from the Company Relocation Product Development Research Awards mechanism. The PDRC considered the application again at its March 17, 2020, meeting and recommended it to the PIC. Additionally, within this mechanism, the PDRC recommended this application to the PIC rather than another application that received a better score. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the und	ersigned authority, on
the 6 day of May	, 2020,
by WAYNE R. ROBERTS.	
	MELANIE CLEVELAND
Welanie Cleveland	NOTARY PUBLIC S IDM 131757703
Meranie Cleverana	Comm. Exp. 10-08-2022
Melanie Cleveland	NOTARY WITHOUT BOND
Notary Public, State of Texas	

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:46 PM

FY: 2020 **CYCLE:** 1

PROGRAM: Product Development

MECHANISM: Company Relocation Product Development Research Awards

APPLICATION ID: DP200034

APPLICATION TITLE: CARGo: a CAR-T cell program targeting HLA-G - a novel immune checkpoint and tumor specific antigen for advanced clear cell renal and ovarian carcinomas

APPLICANT NAME: Wain-Hobson, Simon - ORGANIZATION: Invectys USA Inc

Category	Compliance Requirement	Information	Attestation Date
re-Receipt	RFA approved by CPDO	05/07/2019	12/12/2019
	RFA published in Texas.gov eGrants	05/16/2019	12/12/2019
	CPRIT Application Receipt System (CARS) opened	06/27/2019	12/12/2019
	CPRIT Application Receipt System (CARS) closed	08/07/2019	12/12/2019
	Date application submitted	08/07/2019	12/13/2019
	Method of submission	CARS	12/13/2019
	Within receipt period	YES	12/13/2019
	Request for extension to submit application after CARS closed	NA	12/13/2019
	Request for extension for late application submission accepted	NA	12/13/2019
	Submission of application fee	YES	01/21/2020
Receipt, Referral, and Assignment	Administrative review notification	NA	12/13/2019
	Donation(s) made to CPRIT / foundation	NO	12/13/2019
	Assigned to primary reviewers	08/30/2019	12/13/2019
	Applicant notified of review panel assignment	08/22/2019	12/12/2019
	Primary Reviewer 1 COI signed	08/24/2019	12/13/2019
	Primary (Advocate) Reviewer 2 COI signed	08/21/2019	12/13/2019
	Primary Reviewer 3 COI signed	08/21/2019	12/13/2019
	Primary Reviewer 4 COI signed	08/22/2019	12/13/2019
Screening Teleconference Meeting	Primary Reviewer 1 critique submitted	03/13/2020	12/13/2019
0	Primary (Advocate) Reviewer 2 critique submitted	03/17/2020	12/13/2019
	Primary Reviewer 3 critique submitted	03/17/2020	12/13/2019
	Primary Reviewer 3 critique submitted	03/17/2020	12/13/2019
	COI indicated by non-primary reviewer	NONE	12/13/2019
	COI recused from participation	NA NA	12/13/2019
	Screening Teleconference Meeting	09/25/2019	12/13/2019
	Post-Screening Teleconference score report	09/25/2019	12/12/2019
	Post review statements signed	10/24/2019	12/12/2019
	Third Party Observer Report	09/30/2019	12/12/2019
	Recommended for On-Site Meeting	YES	12/13/2019
Peer Review Meeting	COI indicated by non-primary reviewer	NONE	12/13/2019
	COI recused from participation	NA	12/13/2019
	Peer Review Meeting	03/17/2020	12/13/2019
	Peer Review Meeting End Date	10/25/2019	12/13/2019
	Post review statements signed	10/30/2019	12/13/2019
	Third Party Observer Report	11/13/2019	01/16/2020
	Score report delivered to CPDO	11/01/2019	12/13/2019
	Recommended for due diligence and IP review	YES	12/13/2019
Due Diligence and IP Review	Final due diligence review submitted to PDRC	12/11/2019	01/24/2020
	Intellectual Property conflict check	11/01/2019	01/24/2020
	Final intellectual property review submitted	12/10/2019	01/24/2020
Final PDRC Recommendation	COI indicated by PDRC member	NONE	01/16/2020
	COI recused from participation	NA	01/16/2020
	Due Diligence Evaluation Meeting / PDRC Meeting	01/13/2020	01/16/2020
	Third Party Observer Report	01/15/2020	01/23/2020
	Recommended for grant award	Other: NO ACTION	01/16/2020
	PDRC Chair Notification to PIC and OC	01/24/2020	01/24/2020
	COI indicated by PDRC member (DDP-2)	NONE	04/20/2020
	COI recused from participation (DDP-2)	NA	04/20/2020
	Due Diligence Evaluation Mtg / PDRC Mtg (DDP-2)	03/17/2020	04/20/2020
	Third Party Observer Report (DDP-2)	03/31/2020	04/20/2020
	Recommended for grant award (DDP-2)	YES	04/20/2020
	PDRC Chair Notification to PIC and OC (DDP-2)	04/20/2020	04/20/2020
PIC Review	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/2020
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/2020
Oversight Committee	CEO Notification to Oversight Committee	NA NA	03/03/2020
Approval	COI Indicated by Ovarsight Committee member	NA	
	COI Indicated by Oversight Committee member	NA NA	
	COI Recused from participation	NA NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	



CEO AFFIDAVIT Application RR200039 Recruitment of First-Time, Tenure-Track Faculty Members Nomination of Liela Romero, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received 19 applications in response to this RFA during cycles 20.7 through 20.9, including three applications that were withdrawn. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

One application submitted under this RFA, RR200050, was withdrawn by the applicant after the Scientific Review Council recommended the application to the PIC. Therefore, the PIC did not consider this application during its meeting on May 5, 2020.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

APPLICATION PEDIGREE Date and time exported: 05/05/2020 12:56 PM

AFFEICATION FEDIGICE	Date and time exported. 05/05/2020 12		
FY:	2020		
CYCLE:	1		
PROGRAM: MECHANISM:	Recruitment Recruitment of First-Time, Tenure-Track Fac	ulty Mambars	
APPLICATION ID:	RR200039	uity Wembers	
APPLICATION TITLE	Synthesis and Evaluation of Polyhalogenated	d Terpene Natural Produ	ucts as DNMT1 Inhibitors:
APPLICANT NAME: ORGANIZATION:	Nordt, Lee Baylor University		
PANEL NAME:	Recruitment FY20_Cycle 7		
Category	Compliance Requirement	Information 06/18/2019	Attestation Date 09/13/2019
Pre-Receipt	RFA Approved by CSO	00/18/2019	09/15/2019
	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	12/23/2019	03/12/2020
	CPRIT Application Receipt Cycle closed	01/21/2020	03/12/2020
	Date application submitted	01/18/2020	03/12/2020
	Method of submission	CARS	03/12/2020
	Within receipt period	YES	03/12/2020
Possint Referral and Assignment	Administrative review notification	NA	03/12/2020
Receipt, Referral, and Assignment		NO	03/12/2020
	Donation(s) made to CPRIT / foundation	01/31/2020	03/12/2020
	Assigned to primary reviewers Applicant notified of review panel	NA	03/12/2020
	assignment	01/29/2020	03/12/2020
	Primary Reviewer 1 COI signed	01/24/2020	03/12/2020
	Primary Reviewer 2 COI signed	02/05/2020	03/12/2020
Peer Review Meeting	Primary Reviewer 1 critique submitted	02/12/2020	03/12/2020
	Primary Reviewer 2 critique submitted	NONE	03/12/2020
	COI indicated by non-primary reviewer		
	COI recused from participation	NA	03/12/2020
	Discussed at Peer Review Meeting	YES	03/12/2020
	Peer Review Meeting	02/13/2020	03/12/2020
	Post review statements signed	02/20/2020	03/12/2020
	Third Party Observer Report	02/18/2020	03/12/2020
	Score report delivered to CSO	02/21/2020	03/12/2020
	Recommended for SRC review	YES	03/12/2020
Final SRC Recommandation		NONE	03/12/2020
Final SRC Recommendation	COI indicated by SRC member	NA	03/12/2020
	COI recused from participation	02/13/2020	03/12/2020
	SRC Meeting	02/18/2020	03/12/2020
	Third Party Observer Report	YES	03/12/2020
	Recommended for grant award	04/13/2020	04/13/2020
	SRC Chair Notification to PIC and OC Candidate not accepted asst. prof. tenure	YES	05/05/2020
PIC Review	track position prior to SRC date	None	05/05/2020
	COI indicated by PIC member		
	COI recused from participation	NA	05/05/2020
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/2020
Oversight Committee Approval	CEO Notification to Oversight Committee COI Indicated by Oversight Committee	NA NA	
	member	IAN	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation Presented to CPRIT Oversight Committee	NA NA	
	Award approved by Oversight Committee	NO NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	
Comments:			
Comments:			Created Date
No Comment			



CEO AFFIDAVIT Application RR200040 Recruitment of First-Time, Tenure-Track Faculty Members Nomination of Eric Van Nostrand, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received 19 applications in response to this RFA during cycles 20.7 through 20.9, including three applications that were withdrawn. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

One application submitted under this RFA, RR200050, was withdrawn by the applicant after the Scientific Review Council recommended the application to the PIC. Therefore, the PIC did not consider this application during its meeting on May 5, 2020.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. koberts,

CEO, Cancer Prevention and Research Institute of Texas

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:46 PM

2020 FY: **CYCLE:** 1

PROGRAM: Recruitment

Recruitment of First-Time, Tenure-Track Faculty Members **MECHANISM:**

APPLICATION ID: RR200040

APPLICATION TITLE: First-Time, Tenure-Track: Dr. Eric Van Nostrand

APPLICANT NAME: Dickinson, Mary

Baylor College of Medicine **ORGANIZATION:**

Category	Compliance Requirement	Information	Attestation
			Date
Pre-Receipt	RFA Approved by CSO	06/18/2019	09/13/2019
	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	12/23/2019	03/12/2020
	CPRIT Application Receipt Cycle closed	01/21/2020	03/12/2020
	Date application submitted	01/21/2020	03/12/2020
	Method of submission	CARS	03/12/2020
	Within receipt period	YES	03/12/2020
Receipt, Referral, and Assignment	Administrative review notification	NA	03/12/2020
	Donation(s) made to CPRIT / foundation	NO	03/12/2020
	Assigned to primary reviewers	01/31/2020	03/12/2020
	Applicant notified of review panel assignment	NA	03/12/2020
	Primary Reviewer 1 COI signed	01/24/2020	03/12/2020
	Primary Reviewer 2 COI signed	01/29/2020	03/12/202
Peer Review Meeting	Primary Reviewer 1 critique submitted	02/12/2020	03/12/2020
	Primary Reviewer 2 critique submitted	02/06/2020	03/12/2020
	COI indicated by non-primary reviewer	NONE	03/12/202
	COI recused from participation	NA	03/12/202
	Discussed at Peer Review Meeting	YES	03/12/202
	Peer Review Meeting	02/13/2020	03/12/202
	Post review statements signed	02/20/2020	03/12/202
	Third Party Observer Report	02/18/2020	03/12/202
	Score report delivered to CSO	02/21/2020	03/12/2020
	Recommended for SRC review	YES	03/12/2020
Final SRC Recommendation	COI indicated by SRC member	NONE	03/12/202
	COI recused from participation	NA	03/12/2020
	SRC Meeting	02/13/2020	03/12/202
	Third Party Observer Report	02/18/2020	03/12/202
	Recommended for grant award	YES	03/12/2020
	SRC Chair Notification to PIC and OC	04/13/2020	04/13/202
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	05/05/202
	COI indicated by PIC member	None	05/05/202
	COI recused from participation	NA	05/05/202
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/202
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
•	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA NA	
	Advance authority approved by Oversight Committee		



CEO AFFIDAVIT Application RR200042 Recruitment of Rising Stars Nomination of Ken Wang, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Rising Stars* Request for Applications (RFA). CPRIT received five applications in response to this RFA during cycles 20.7 through 20.9. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:46 PM

FY: 2020 **CYCLE:** 1

PROGRAM: Recruitment

MECHANISM: Recruitment of Rising Stars

APPLICATION ID: RR200042

APPLICATION TITLE: Nomination of Ken Kang-Hsin Wang, Ph.D. for a CPRIT Rising Star Award

APPLICANT NAME: Lee, W. P. Andrew

ORGANIZATION: The University of Texas Southwestern Medical Center

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/18/2019	09/13/2019
	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	01/22/2020	03/24/2020
	CPRIT Application Receipt Cycle closed	02/20/2020	03/24/2020
	Date application submitted	01/22/2020	03/25/2020
	Method of submission	CARS	03/25/2020
	Within receipt period	YES	03/25/2020
Receipt, Referral, and Assignment	Administrative review notification	NA	03/25/2020
	Donation(s) made to CPRIT / foundation	NO	03/25/2020
	Assigned to primary reviewers	03/02/2020	03/25/2020
	Applicant notified of review panel assignment	NA	03/24/2020
	Primary Reviewer 1 COI signed	02/26/2020	03/25/2020
	Primary Reviewer 2 COI signed	02/25/2020	03/25/2020
Peer Review Meeting	Primary Reviewer 1 critique submitted	03/09/2020	03/25/2020
	Primary Reviewer 2 critique submitted	03/04/2020	03/25/2020
	COI indicated by non-primary reviewer	NONE	03/25/2020
	COI recused from participation	NA	03/25/2020
	Discussed at Peer Review Meeting	YES	03/25/2020
	Peer Review Meeting	03/12/2020	03/25/2020
	Post review statements signed	03/16/2020	03/25/2020
	Third Party Observer Report	03/20/2020	03/25/2020
	Score report delivered to CSO	03/20/2020	03/25/2020
	Recommended for SRC review	YES	03/25/2020
Final SRC Recommendation	COI indicated by SRC member	NONE	03/25/2020
	COI recused from participation	NA	03/25/2020
	SRC Meeting	03/12/2020	03/25/2020
	Third Party Observer Report	03/20/2020	03/25/2020
	Recommended for grant award	YES	03/25/2020
	SRC Chair Notification to PIC and OC	04/13/2020	04/13/2020
PIC Review	Candidate not accepted position prior to SRC date	YES	05/05/2020
	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/2020
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/2020
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee		

CPRIT retains the identity of the attesting party.



CEO AFFIDAVIT Application RR200043 Recruitment of Established Investigators Nomination of Tanmay Lele, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Established Investigators* Request for Applications (RFA). CPRIT received eight applications in response to this RFA during cycles 20.7 through 20.9. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis
SWORN to and SUBSCRIBED before me, the undersigned authority, on the
Melanie Cleveland Notary Public, State of Texas MELANIE CLEVELAND NOTARY WITHOUT BOND MELANIE CLEVELAND NOTARY WITHOUT BOND

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:46 PM

FY: 2020 **CYCLE:** 1

PROGRAM: Recruitment

MECHANISM: Recruitment of Established Investigators

APPLICATION ID: RR200043

APPLICATION TITLE: Dr Tanmay Lele: Nuclear Dysmorphia in Pediatric Cancers

APPLICANT NAME: Banks, Margaret K

ORGANIZATION: Texas A&M Engineering Experiment Station

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/18/2019	09/13/2019
	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	01/22/2020	03/24/2020
	CPRIT Application Receipt Cycle closed	02/20/2020	03/24/2020
	Date application submitted	02/20/2020	03/25/2020
	Method of submission	CARS	03/25/2020
	Within receipt period	YES	03/25/2020
Receipt, Referral, and Assignment	Administrative review notification	NA	03/25/2020
	Donation(s) made to CPRIT / foundation	NO	03/25/2020
	Assigned to primary reviewers	03/02/2020	03/25/2020
	Applicant notified of review panel assignment	NA	03/24/2020
	Primary Reviewer 1 COI signed	02/25/2020	03/25/2020
	Primary Reviewer 2 COI signed	02/25/2020	03/25/2020
Peer Review Meeting	Primary Reviewer 1 critique submitted	03/10/2020	03/25/2020
	Primary Reviewer 2 critique submitted	03/06/2020	03/25/2020
	COI indicated by non-primary reviewer	NONE	03/25/2020
	COI recused from participation	NA	03/25/2020
	Discussed at Peer Review Meeting	YES	03/25/2020
	Peer Review Meeting	03/12/2020	03/25/2020
	Post review statements signed	03/16/2020	03/25/2020
	Third Party Observer Report	03/20/2020	03/25/2020
	Score report delivered to CSO	03/20/2020	03/25/2020
	Recommended for SRC review	YES	03/25/2020
Final SRC Recommendation	COI indicated by SRC member	NONE	03/25/2020
	COI recused from participation	NA	03/25/2020
	SRC Meeting	03/12/2020	03/25/2020
	Third Party Observer Report	03/20/2020	03/25/2020
	Recommended for grant award	YES	03/25/2020
	SRC Chair Notification to PIC and OC	04/13/2020	04/13/2020
PIC Review	Candidate not accepted position prior to SRC date	YES	05/05/2020
	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/2020
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/2020
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
* *	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA NA	
	Advance authority approved by Oversight Committee		

CPRIT retains the identity of the attesting party.



CEO AFFIDAVIT Application RR200045 Recruitment of First-Time, Tenure-Track Faculty Members Nomination of Robert Hillman, M.D., Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received 19 applications in response to this RFA during cycles 20.7 through 20.9, including three applications that were withdrawn. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

One application submitted under this RFA, RR200050, was withdrawn by the applicant after the Scientific Review Council recommended the application to the PIC. Therefore, the PIC did not consider this application during its meeting on May 5, 2020.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:47 PM

FY: 2020 **CYCLE:** 1

PROGRAM: Recruitment

MECHANISM: Recruitment of First-Time, Tenure-Track Faculty Members

APPLICATION ID: RR200045

APPLICATION TITLE: Recruitment of First-Time, Tenure-Track Faculty Members- Robert Tyler Hillman

APPLICANT NAME: Draetta, Gulio

ORGANIZATION: The University of Texas M. D. Anderson Cancer Center

Category	Compliance Requirement	Information	Attestation
	•		Date
Pre-Receipt	RFA Approved by CSO	06/18/2019	09/13/2019
	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	12/23/2019	03/12/2020
	CPRIT Application Receipt Cycle closed	01/21/2020	03/12/2020
	Date application submitted	01/17/2020	03/12/2020
	Method of submission	CARS	03/12/2020
	Within receipt period	YES	03/12/2020
Receipt, Referral, and Assignment	Administrative review notification	NA	03/12/2020
	Donation(s) made to CPRIT / foundation	NO	03/12/2020
	Assigned to primary reviewers	01/31/2020	03/12/2020
	Applicant notified of review panel assignment	NA	03/12/2020
	Primary Reviewer 1 COI signed	01/24/2020	03/12/2020
	Primary Reviewer 2 COI signed	01/25/2020	03/12/2020
Peer Review Meeting	Primary Reviewer 1 critique submitted	02/11/2020	03/12/2020
8	Primary Reviewer 2 critique submitted	02/10/2020	03/12/2020
	COI indicated by non-primary reviewer	NONE	03/12/2020
	COI recused from participation	NA	03/12/2020
	Discussed at Peer Review Meeting	YES	03/12/2020
	Peer Review Meeting	02/13/2020	03/12/2020
	Post review statements signed	02/20/2020	03/12/2020
	Third Party Observer Report	02/18/2020	03/12/2020
	Score report delivered to CSO	02/21/2020	03/12/2020
	Recommended for SRC review	YES	03/12/2020
Final SRC Recommendation	COI indicated by SRC member	NONE	03/12/2020
	COI recused from participation	NA	03/12/2020
	SRC Meeting	02/13/2020	03/12/2020
	Third Party Observer Report	02/18/2020	03/12/2020
	Recommended for grant award	YES	03/12/2020
	SRC Chair Notification to PIC and OC	04/13/2020	04/13/2020
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	05/05/2020
	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/2020
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/2020
Oversight Committee Approval	CEO Notification to Oversight Committee	NA NA	
	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Commit		

CPRIT retains the identity of the attesting party.



CEO AFFIDAVIT Application RR200046 Recruitment of Established Investigators Nomination of Henry Charles Manning, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Established Investigators* Request for Applications (RFA). CPRIT received eight applications in response to this RFA during cycles 20.7 through 20.9. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:47 PM

FY: 2020 **CYCLE:** 1

PROGRAM: Recruitment

MECHANISM: Recruitment of Established Investigators

APPLICATION ID: RR200046

APPLICATION TITLE: Recruitment of Established Investigators-Charles Manning

APPLICANT NAME: Draetta, Gulio

ORGANIZATION: The University of Texas M. D. Anderson Cancer Center

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/18/2019	09/13/2019
	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	12/23/2019	03/12/2020
	CPRIT Application Receipt Cycle closed	01/21/2020	03/12/2020
	Date application submitted	01/17/2020	03/12/2020
	Method of submission	CARS	03/12/2020
	Within receipt period	YES	03/12/2020
Receipt, Referral, and Assignment	Administrative review notification	NA	03/12/2020
	Donation(s) made to CPRIT / foundation	NO	03/12/2020
	Assigned to primary reviewers	01/31/2020	03/12/2020
	Applicant notified of review panel assignment	NA	03/12/2020
	Primary Reviewer 1 COI signed	01/27/2020	03/12/2020
	Primary Reviewer 2 COI signed	01/29/2020	03/12/2020
Peer Review Meeting	Primary Reviewer 1 critique submitted	02/11/2020	03/12/2020
	Primary Reviewer 2 critique submitted	02/10/2020	03/12/2020
	COI indicated by non-primary reviewer	NONE	03/12/2020
	COI recused from participation	NA	03/12/2020
	Discussed at Peer Review Meeting	YES	03/12/2020
	Peer Review Meeting	02/13/2020	03/12/2020
	Post review statements signed	02/20/2020	03/12/2020
	Third Party Observer Report	02/18/2020	03/12/2020
	Score report delivered to CSO	02/21/2020	03/12/2020
	Recommended for SRC review	YES	03/12/2020
Final SRC Recommendation	COI indicated by SRC member	NONE	03/12/2020
	COI recused from participation	NA	03/12/2020
	SRC Meeting	02/13/2020	03/12/2020
	Third Party Observer Report	02/18/2020	03/12/2020
	Recommended for grant award	YES	03/12/2020
	SRC Chair Notification to PIC and OC	04/13/2020	04/13/2020
PIC Review	Candidate not accepted position prior to SRC date	YES	05/05/2020
	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/2020
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/2020
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
11	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA NA	
	Advance authority approved by Oversight Committee		

CPRIT retains the identity of the attesting party.



CEO AFFIDAVIT Application RR200054 Recruitment of First-Time, Tenure-Track Faculty Members Nomination of Megan Whisenant, Ph.D, RN, FNP-BC

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received 19 applications in response to this RFA during cycles 20.7 through 20.9, including three applications that were withdrawn. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

One application submitted under this RFA, RR200050, was withdrawn by the applicant after the Scientific Review Council recommended the application to the PIC. Therefore, the PIC did not consider this application during its meeting on May 5, 2020.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:47 PM

2020 FY: **CYCLE:** 1

PROGRAM: Recruitment

MECHANISM: Recruitment of First-Time, Tenure-Track Faculty Members

APPLICATION ID: RR200054

APPLICATION TITLE: Meagan Whisenant Recruitment of First-Time Tenure-Track Faculty

Blackburn, Michael R **APPLICANT NAME:**

ORGANIZATION: The University of Texas Health Science Center at Houston

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/18/2019	09/13/2019
•	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	01/22/2020	03/24/202
	CPRIT Application Receipt Cycle closed	02/20/2020	03/24/202
	Date application submitted	02/19/2020	03/25/202
	Method of submission	CARS	03/25/202
	Within receipt period	YES	03/25/202
Receipt, Referral, and Assignment	Administrative review notification	02/26/2020	03/25/202
	2nd Administrative review notification	02/28/2020	03/25/202
	Donation(s) made to CPRIT / foundation	NO	03/25/202
	Assigned to primary reviewers	03/02/2020	03/25/202
	Applicant notified of review panel assignment	NA	03/24/202
	Primary Reviewer 1 COI signed	02/25/2020	03/25/202
	Primary Reviewer 2 COI signed	02/26/2020	03/25/202
Peer Review Meeting	Primary Reviewer 1 critique submitted	03/11/2020	03/25/202
	Primary Reviewer 2 critique submitted	03/10/2020	03/25/202
	COI indicated by non-primary reviewer	NONE	03/25/202
	COI recused from participation	NA	03/25/202
	Discussed at Peer Review Meeting	YES	03/25/202
	Peer Review Meeting	03/12/2020	03/25/202
	Post review statements signed	03/16/2020	03/25/202
	Third Party Observer Report	03/20/2020	03/25/202
	Score report delivered to CSO	03/20/2020	03/25/202
	Recommended for SRC review	YES	03/25/202
Final SRC Recommendation	COI indicated by SRC member	NONE	03/25/202
	COI recused from participation	NA	03/25/202
	SRC Meeting	03/12/2020	03/25/202
	Third Party Observer Report	03/20/2020	03/25/202
	Recommended for grant award	YES	03/25/202
	SRC Chair Notification to PIC and OC	04/13/2020	04/13/202
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	05/05/202
	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/202
	PIC Review Meeting	05/05/2020	05/05/202
	Recommended for grant award	YES	05/05/202
Oversight Committee Approva		NA	
	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

CPRIT retains the identity of the attesting party.



CEO AFFIDAVIT Application RR200056 Recruitment of Rising Stars Nomination of Veronika Fedirko, MPH, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Rising Stars* Request for Applications (RFA). CPRIT received five applications in response to this RFA during cycles 20.7 through 20.9. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:47 PM

FY: 2020 **CYCLE:** 1

PROGRAM: Recruitment

MECHANISM: Recruitment of Rising Stars

APPLICATION ID: RR200056

APPLICATION TITLE: Recruitment of Rising Stars-Veronika Fedirko

APPLICANT NAME: Draetta, Gulio

ORGANIZATION: The University of Texas M. D. Anderson Cancer Center

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/18/2019	09/13/2019
	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	01/22/2020	03/24/2020
	CPRIT Application Receipt Cycle closed	02/20/2020	03/24/2020
	Date application submitted	02/20/2020	03/25/2020
	Method of submission	CARS	03/25/2020
	Within receipt period	YES	03/25/2020
Receipt, Referral, and Assignment	Administrative review notification	NA	03/25/2020
	Donation(s) made to CPRIT / foundation	NO	03/25/2020
	Assigned to primary reviewers	03/02/2020	03/25/2020
	Applicant notified of review panel assignment	NA	03/24/2020
	Primary Reviewer 1 COI signed	02/26/2020	03/25/2020
	Primary Reviewer 2 COI signed	02/25/2020	03/25/2020
Peer Review Meeting	Primary Reviewer 1 critique submitted	03/10/2020	03/25/2020
	Primary Reviewer 2 critique submitted	03/04/2020	03/25/2020
	COI indicated by non-primary reviewer	NONE	03/25/2020
	COI recused from participation	NA	03/25/2020
	Discussed at Peer Review Meeting	YES	03/25/2020
	Peer Review Meeting	03/12/2020	03/25/2020
	Post review statements signed	03/16/2020	03/25/2020
	Third Party Observer Report	03/20/2020	03/25/2020
	Score report delivered to CSO	03/20/2020	03/25/2020
	Recommended for SRC review	YES	03/25/2020
Final SRC Recommendation	COI indicated by SRC member	NONE	03/25/2020
	COI recused from participation	NA	03/25/2020
	SRC Meeting	03/12/2020	03/25/2020
	Third Party Observer Report	03/20/2020	03/25/2020
	Recommended for grant award	YES	03/25/2020
	SRC Chair Notification to PIC and OC	04/13/2020	04/13/2020
PIC Review	Candidate not accepted position prior to SRC date	YES	05/05/2020
	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/2020
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/2020
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA NA	
	Advance authority approved by Oversight Committee		

CPRIT retains the identity of the attesting party.



CEO AFFIDAVIT Application RR200057 Recruitment of Established Investigators Nomination of Dean Felsher, M.D., Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Established Investigators* Request for Applications (RFA). CPRIT received eight applications in response to this RFA during cycles 20.7 through 20.9. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the undersigned authority, on the	
Melanie Cleveland Notary Public, State of Texas MELANIE CLEVELAND NOTARY PUBLIC DIVISITY 7/03 Slate of lexas Comm. Exp. 10-08-2022 NOTARY WITHOUT BOND	

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:47 PM

FY: 2020 **CYCLE:** 1

PROGRAM: Recruitment

MECHANISM: Recruitment of Established Investigators

APPLICATION ID: RR200057

APPLICATION TITLE: Recruitment of Established Investigators-Dean Felsher

APPLICANT NAME: Draetta, Gulio

ORGANIZATION: The University of Texas M. D. Anderson Cancer Center

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/18/2019	09/13/2019
·	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	01/22/2020	03/24/2020
	CPRIT Application Receipt Cycle closed	02/20/2020	03/24/2020
	Date application submitted	02/20/2020	03/25/2020
	Method of submission	CARS	03/25/2020
	Within receipt period	YES	03/25/2020
Receipt, Referral, and Assignment	Administrative review notification	NA	03/25/2020
	Donation(s) made to CPRIT / foundation	NO	03/25/2020
	Assigned to primary reviewers	03/02/2020	03/25/2020
	Applicant notified of review panel assignment	NA	03/24/2020
	Primary Reviewer 1 COI signed	02/25/2020	03/25/2020
	Primary Reviewer 2 COI signed	02/25/2020	03/25/2020
Peer Review Meeting	Primary Reviewer 1 critique submitted	03/09/2020	03/25/2020
	Primary Reviewer 2 critique submitted	03/10/2020	03/25/2020
	COI indicated by non-primary reviewer	Margaret Tempero	03/25/2020
	COI recused from participation	YES	03/25/2020
	Discussed at Peer Review Meeting	YES	03/25/2020
	Peer Review Meeting	03/12/2020	03/25/2020
	Post review statements signed	03/16/2020	03/25/2020
	Third Party Observer Report	03/20/2020	03/25/2020
	Score report delivered to CSO	03/20/2020	03/25/2020
	Recommended for SRC review	YES	03/25/2020
Final SRC Recommendation	COI indicated by SRC member	Margaret Tempero	03/25/2020
	COI recused from participation	YES	03/25/2020
	SRC Meeting	03/12/2020	03/25/2020
	Third Party Observer Report	03/20/2020	03/25/2020
	Recommended for grant award	YES	03/25/2020
	SRC Chair Notification to PIC and OC	04/13/2020	04/13/2020
PIC Review	Candidate not accepted position prior to SRC date	YES	05/05/2020
	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/2020
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/2020
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA NA	
	Advance authority approved by Oversight Committ		

CPRIT retains the identity of the attesting party.



CEO AFFIDAVIT Application RR200059 Recruitment of First-Time, Tenure-Track Faculty Members Nomination of Klementina Fon Tracer, DVM, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received 19 applications in response to this RFA during cycles 20.7 through 20.9, including three applications that were withdrawn. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

One application submitted under this RFA, RR200050, was withdrawn by the applicant after the Scientific Review Council recommended the application to the PIC. Therefore, the PIC did not consider this application during its meeting on May 5, 2020.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts.

CEO, Cancer Prevention and Research Institute of Texas

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:47 PM

FY: 2020 **CYCLE:** 1

PROGRAM: Recruitment

MECHANISM: Recruitment of First-Time, Tenure-Track Faculty Members

APPLICATION ID: RR200059

APPLICATION TITLE: Recruitment of Dr.Klementina Fon Tacer

APPLICANT NAME: Schovanec, Lawrence
ORGANIZATION: Texas Tech University
PANEL NAME: Recruitment FY20_Cycle 8

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/18/2019	09/13/2019
	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	01/22/2020	03/24/2020
	CPRIT Application Receipt Cycle closed	02/20/2020	03/24/2020
	Date application submitted	02/20/2020	03/25/2020
	Method of submission	CARS	03/25/2020
	Within receipt period	YES	03/25/2020
Receipt, Referral, and Assignment	Administrative review notification	02/26/2020	03/25/2020
	Donation(s) made to CPRIT / foundation	NO	03/25/2020
	Assigned to primary reviewers	03/02/2020	03/25/2020
	Applicant notified of review panel assignment	NA	03/24/2020
	Primary Reviewer 1 COI signed	02/25/2020	03/25/2020
	Primary Reviewer 2 COI signed	02/25/2020	03/25/2020
Peer Review Meeting	Primary Reviewer 1 critique submitted	03/09/2020	03/25/2020
	Primary Reviewer 2 critique submitted	03/10/2020	03/25/2020
	COI indicated by non-primary reviewer	NONE	03/25/2020
	COI recused from participation	NA	03/25/2020
	Discussed at Peer Review Meeting	YES	03/25/2020
	Peer Review Meeting	03/12/2020	03/25/2020
	Post review statements signed	03/16/2020	03/25/2020
	Third Party Observer Report	03/20/2020	03/25/2020
	Score report delivered to CSO	03/20/2020	03/25/2020
	Recommended for SRC review	YES	03/25/2020
Final SRC Recommendation	COI indicated by SRC member	NONE	03/25/2020
	COI recused from participation	NA	03/25/2020
	SRC Meeting	03/12/2020	03/25/2020
	Third Party Observer Report	03/20/2020	03/25/2020
	Recommended for grant award	YES	03/25/2020
	SRC Chair Notification to PIC and OC	04/13/2020	04/13/2020
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	05/05/2020
	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/2020
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/2020
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee		

CPRIT retains the identity of the attesting party.



CEO AFFIDAVIT Application RR200065 Recruitment of First-Time, Tenure-Track Faculty Members Nomination of Jason Lee, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received 19 applications in response to this RFA during cycles 20.7 through 20.9, including three applications that were withdrawn. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

One application submitted under this RFA, RR200050, was withdrawn by the applicant after the Scientific Review Council recommended the application to the PIC. Therefore, the PIC did not consider this application during its meeting on May 5, 2020.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Røberts,

CEO, Cancer Prevention and Research Institute of Texas

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:47 PM

FY: 2020 **CYCLE:** 1

PROGRAM: Recruitment

MECHANISM: Recruitment of First-Time, Tenure-Track Faculty Members

APPLICATION ID: RR200065

APPLICATION TITLE: First-Time, Tenure-Track Recruit: Dr. Jason Lee

APPLICANT NAME: Dickinson, Mary

Baylor College of Medicine **ORGANIZATION:**

Category	Compliance Requirement	Information	Attestation
Pre-Receipt	RFA Approved by CSO	06/18/2019	Date 09/13/2019
Те-жесере	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	02/21/2020	04/15/2020
	CPRIT Application Receipt Cycle closed	03/20/2020	04/15/2020
	Date application submitted	03/17/2020	04/15/2020
	Method of submission	CARS	04/15/2020
		YES	04/15/2020
Daggint Dafannal	Within receipt period	NA	04/15/2020
Receipt, Referral, and Assignment	Administrative review notification		
	Donation(s) made to CPRIT / foundation	NO	04/15/2020
	Assigned to primary reviewers	03/31/2020	04/15/202
	Applicant notified of review panel assignment	NA	04/15/202
	Primary Reviewer 1 COI signed	03/24/2020	04/15/202
	Primary Reviewer 2 COI signed	03/27/2020	04/15/202
Peer Review Meeting	Primary Reviewer 1 critique submitted	04/07/2020	04/15/2020
	Primary Reviewer 2 critique submitted	04/07/2020	04/15/2020
	COI indicated by non-primary reviewer	NONE	04/15/202
	COI recused from participation	NA	04/15/202
	Discussed at Peer Review Meeting	YES	04/15/202
	Peer Review Meeting	04/09/2020	04/15/202
	Post review statements signed	04/14/2020	04/15/202
	Third Party Observer Report	04/13/2020	04/15/202
	Score report delivered to CSO	04/14/2020	04/15/2020
	Recommended for SRC review	YES	04/15/2020
Final SRC Recommendation	COI indicated by SRC member	NONE	04/15/202
	COI recused from participation	NA	04/15/202
	SRC Meeting	04/09/2020	04/15/202
	Third Party Observer Report	04/13/2020	04/15/202
	Recommended for grant award	YES	04/15/202
	SRC Chair Notification to PIC and OC	04/13/2020	04/15/202
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	05/05/202
	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/2020
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/202
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA NA	
	Advance authority approved by Oversight Committee		

CPRIT retains the identity of the attesting party.



CEO AFFIDAVIT Application RR200070 Recruitment of First-Time, Tenure-Track Faculty Members Nomination of Matthew Parker, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received 19 applications in response to this RFA during cycles 20.7 through 20.9, including three applications that were withdrawn. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

One application submitted under this RFA, RR200050, was withdrawn by the applicant after the Scientific Review Council recommended the application to the PIC. Therefore, the PIC did not consider this application during its meeting on May 5, 2020.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:47 PM

FY: 2020 **CYCLE:** 1

PROGRAM: Recruitment

MECHANISM: Recruitment of First-Time, Tenure-Track Faculty Members

APPLICATION ID: RR200070

APPLICATION TITLE: Recruitment of Matthew Parker for a CPRIT First-Time, Tenure-Track Faculty Member Award

APPLICANT NAME: Lee, W. P. Andrew

ORGANIZATION: The University of Texas Southwestern Medical Center

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/18/2019	09/13/2019
re receipt	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	02/21/2020	04/15/2020
	CPRIT Application Receipt Cycle closed	03/20/2020	04/15/2020
	Date application submitted	03/19/2020	04/15/2020
	Method of submission	CARS	04/15/2020
	Within receipt period	YES	04/15/2020
Receipt, Referral,	within receipt period	03/25/2020	04/15/2020
and Assignment	Administrative review notification		
	Donation(s) made to CPRIT / foundation	NO	04/15/2020
	Assigned to primary reviewers	03/31/2020	04/15/2020
	Applicant notified of review panel assignment	NA	04/15/2020
	Primary Reviewer 1 COI signed	03/30/2020	04/15/2020
	Primary Reviewer 2 COI signed	03/27/2020	04/15/2020
Peer Review Meeting	Primary Reviewer 1 critique submitted	04/08/2020	04/15/2020
	Primary Reviewer 2 critique submitted	04/08/2020	04/15/2020
	COI indicated by non-primary reviewer	NONE	04/15/2020
	COI recused from participation	NA	04/15/2020
	Discussed at Peer Review Meeting	YES	04/15/2020
	Peer Review Meeting	04/09/2020	04/15/2020
	Post review statements signed	04/14/2020	04/15/2020
	Third Party Observer Report	04/13/2020	04/15/2020
	Score report delivered to CSO	04/14/2020	04/15/2020
	Recommended for SRC review	YES	04/15/2020
Final SRC Recommendation	COI indicated by SRC member	NONE	04/15/2020
	COI recused from participation	NA	04/15/2020
	SRC Meeting	04/09/2020	04/15/2020
	Third Party Observer Report	04/13/2020	04/15/2020
	Recommended for grant award	YES	04/15/2020
	SRC Chair Notification to PIC and OC	04/13/2020	04/15/2020
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	05/05/2020
	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/2020
	PIC Review Meeting	05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/2020
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA NA	
	Advance authority approved by Oversight Committee		

CPRIT retains the identity of the attesting party.



CEO AFFIDAVIT Application RR200072 Recruitment of Established Investigators Nomination of Wenyi Wei, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Established Investigators* Request for Applications (RFA). CPRIT received eight applications in response to this RFA during cycles 20.7 through 20.9. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2020: Dr. John Hellerstedt, Department of State Health Services Commissioner, and Dr. James Willson, Chief Scientific Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis
SWORN to and SUBSCRIBED before me, the undersigned authority, on the
Melanie Cleveland Notary Public, State of Texas MELANIE CLEVELAND NOTARY WITHOUT BOND MELANIE CLEVELAND NOTARY WITHOUT BOND

APPLICATION PEDIGREE

Date and time exported: 05/05/2020 12:47 PM

FY: 2020 **CYCLE:** 1

ORGANIZATION:

PROGRAM: Recruitment

MECHANISM: Recruitment of Established Investigators

APPLICATION ID: RR200072

APPLICATION TITLE: Recruitment of Wenyi Wei for a CPRIT Established Investigator Award (REI) **APPLICANT NAME:** Lee, W. P. Andrew

The University of Texas Southwestern Medical Center

PANEL NAME: Recruitment FY20_Cycle 9

PANEL NAME:	Recruitment FY20_Cycle 9		Attestation
Category	Compliance Requirement	Information	Date
Pre-Receipt	RFA Approved by CSO	06/18/2019	09/13/2019
	RFA published in Texas.gov eGrants	06/21/2019	09/13/2019
	CPRIT Application Receipt Cycle opened	02/21/2020	04/15/2020
	CPRIT Application Receipt Cycle closed	03/20/2020	04/15/2020
	Date application submitted	03/19/2020	04/15/2020
	Method of submission	CARS	04/15/2020
	Within receipt period	YES	04/15/2020
Receipt, Referral, and Assignment	Administrative review notification	NA	04/15/2020
	Donation(s) made to CPRIT / foundation	NO	04/15/2020
	Assigned to primary reviewers	03/31/2020	04/15/2020
	Applicant notified of review panel assignment	NA	04/15/2020
		03/24/2020	04/15/2020
	Primary Reviewer 2 COI signed	03/27/2020	04/15/2020
Peer Review Meeting	Primary Reviewer 1 critique submitted	04/06/2020	04/15/2020
	Primary Reviewer 2 critique submitted	04/07/2020	04/15/2020
	COI indicated by non-primary reviewer	Myles Brown	04/15/2020
	COI recused from participation	YES	04/15/2020
	Discussed at Peer Review Meeting	YES	04/15/2020
	Peer Review Meeting	04/09/2020	04/15/2020
		04/14/2020	04/15/2020
		04/13/2020	04/15/2020
		04/14/2020	04/15/2020
	Recommended for SRC review	YES	04/15/2020
Final SRC Recommendation		Myles Brown	04/15/2020
	COI recused from participation	YES	04/15/2020
	SRC Meeting	04/09/2020	04/15/2020
		04/13/2020	04/15/2020
	Recommended for grant award	YES	04/15/2020
	SRC Chair Notification to PIC and OC	04/13/2020	04/15/2020
PIC Review		YES	05/05/2020
110 110 110 11	COI indicated by PIC member	None	05/05/2020
	COI recused from participation	NA	05/05/2020
		05/05/2020	05/05/2020
	Recommended for grant award	YES	05/05/2020
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	03/03/2020
	COI Indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee		

CPRIT retains the identity of the attesting party.